

US3412304 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:38:27

All time stamps listed in this document are displayed in GMT

US3412304

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

[Participant ID](#)

US3412304

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

US3412304

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3412304

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Date of Birth (MMM yyyy)	(b) (6) 1950
Age	70
Age Units	YEARS
Age (Derived)	70
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3412304

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3412304

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412304

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Were any significant conditions reported?

Yes ☒
No ☐

US3412304

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Condition	ALLERGIC RHINITIS - SHRIMP
Start date (dd MMM yyyy)	UN UNK 1955
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 1955
Start Year (derived)	1955
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412304

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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)	

US3412304

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412304

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Condition	GERD
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)	

US3412304

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Condition	OSTEOARTHRITIS - LEFT FOOT AND LOWER BACK
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

US3412304

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Condition	HYPERGLYCEMIA
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)	

US3412304

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 AUG 2020
Time of assessment (00:00-23:59)	9:25 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 9:25
Height (xxx.x)	174.7 cm
Weight (xxx.x)	110.4 kg
BMI (xxx.x)	36.17289 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)	

US3412304

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 AUG 2020

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

US3412304

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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

RETIRED, SOME INTERACTIONS
WITH OTHERS. DOES SHOPPING
AND DINING OUT.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

16 of 2984

US3412304

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 187249

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Height	ND - Not Done
Weight	ND - Not Done

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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)	24 AUG 2020
Time of assessment (00:00-23:59)	09:25 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 09:25
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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)	24 AUG 2020
Time of assessment (00:00-23:59)	10:56 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 10:56
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 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)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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.

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 10:25 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 10:25

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

US3412304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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

Collection date (dd MMM yyyy)	24 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	9:59 (24 HR)
-------------------------------	--------------

Collection date and time (derived)	24 AUG 2020 9:59
------------------------------------	------------------

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Collection date (dd MMM yyyy)			24 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:03	24 AUG 2020 10:03
Nasopharyngeal Swab 2	No		

US3412304

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 11:03

PC Open Date & Time

24 AUG 2020 10:45

PC Close Date & Time

24 AUG 2020 13:15

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	24 AUG 2020 20:31
PC Open Date & Time	24 AUG 2020 14:10
PC Close Date & Time	25 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 20:39

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

26 AUG 2020 20:33

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 21:34

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

28 AUG 2020 20:32

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

97.5 °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

29 AUG 2020 19:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

98.0 °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

30 AUG 2020 20:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

24 AUG 2020 11:04

PC Open Date & Time

24 AUG 2020 10:45

PC Close Date & Time

24 AUG 2020 13:15

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

24 AUG 2020 20:31

PC Open Date & Time

24 AUG 2020 14:10

PC Close Date & Time

25 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

25 AUG 2020 20:40

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

26 AUG 2020 20:34

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

27 AUG 2020 21:34

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

28 AUG 2020 20:33

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

29 AUG 2020 19:40

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

30 AUG 2020 20:19

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 11:05
PC Open Date & Time	24 AUG 2020 10:45
PC Close Date & Time	24 AUG 2020 13:15

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:32
PC Open Date & Time	24 AUG 2020 14:10
PC Close Date & Time	25 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:40
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

50 of 2984

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:34
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2984

EAB) (1725)

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 21:35
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

54 of 2984

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:33
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:40
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:19
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT2

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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)	21 SEP 2020
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 08:05
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)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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)	21 SEP 2020
Time of assessment (00:00-23:59)	09:23 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 09:23
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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) 21 SEP 2020

What was the treatment time? (00:00-23:59) 08:50 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 08:50

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

What was the frequency of the study treatment dosing? ONCE

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

US3412304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 SEP 2020

Collection time (00:00-23:59)

08:24 (24 HR)

Collection date and time (derived)

21 SEP 2020 08:24

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:28	21 SEP 2020 08:28
Nasopharyngeal Swab 2	No		

US3412304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

97.5 °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

21 SEP 2020 09:25

PC Open Date & Time

21 SEP 2020 09:10

PC Close Date & Time

21 SEP 2020 11:40

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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	21 SEP 2020 20:03
PC Open Date & Time	21 SEP 2020 12:35
PC Close Date & Time	22 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

97.1 °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

22 SEP 2020 20:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 20:06

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 20:29

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

97.5 °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

26 SEP 2020 16:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

98.7 °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

27 SEP 2020 20:05

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

21 SEP 2020 09:25

PC Open Date & Time

21 SEP 2020 09:10

PC Close Date & Time

21 SEP 2020 11:40

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

21 SEP 2020 20:03

PC Open Date & Time

21 SEP 2020 12:35

PC Close Date & Time

22 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

22 SEP 2020 20:03

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

23 SEP 2020 20:07

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

24 SEP 2020 20:29

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

25 SEP 2020 20:03

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

26 SEP 2020 16:44

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

27 SEP 2020 20:05

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 09:25
PC Open Date & Time	21 SEP 2020 09:10
PC Close Date & Time	21 SEP 2020 11:40

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:03
PC Open Date & Time	21 SEP 2020 12:35
PC Close Date & Time	22 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

94 of 2984

EAB) (1725)

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:03
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:07
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 20:30
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:03
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 2984

EAB) (1725)

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 16:44
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 ☒

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:05
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3412304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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) _____

US3412304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

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.

US3412304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 OCT 2020
Collection time (00:00-23:59)	08:24 (24 HR)
Collection date and time (derived)	19 OCT 2020 08:24

US3412304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 12:22:06

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 18:05:12

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

31 OCT 2020 17:29:54

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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)	True
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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	08 NOV 2020 22:04:44
Patient Cloud Open Date & Time	07 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	119 of 2984

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 NOV 2020 17:00:59
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 NOV 2020 21:44:29
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 DEC 2020 15:30:57

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

20 DEC 2020 20:58:45

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 20:30:27

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 JAN 2021 17:01:01

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 JAN 2021 09:39:52

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 17:00:40

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

23 JAN 2021 17:01:40

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

30 JAN 2021 19:48:26

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 FEB 2021 11:11:25
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

13 FEB 2021 16:30:22

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 16:39:52

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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	06 MAR 2021 19:22:57
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 10:00:33

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

27 MAR 2021 11:25:50

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

03 APR 2021 07:08:37

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

11 APR 2021 09:49:44

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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	17 APR 2021 16:04:30
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

25 APR 2021 17:00:29

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

01 MAY 2021 17:08:44

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2021 00:01
Patient Cloud Close Date & Time	16 MAY 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission	
Patient Cloud Open Date & Time	14 JUL 2021 00:01
Patient Cloud Close Date & Time	18 JUL 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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="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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission

Patient Cloud Open Date & Time	25 AUG 2021 00:01
--	-------------------

Patient Cloud Close Date & Time	29 AUG 2021 23:59
---	-------------------

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission	
Patient Cloud Open Date & Time	13 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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°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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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°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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 <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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 782
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3412304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:38:27

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		06 MAR 2021 19:23:23

US3412304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

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

THIS WAS NOT INDICATED DUE
TO SUBJECT BEING IN THE
CONVALESCENT PERIOD AT
THE TIME.

US3412304

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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

PATIENT NOT CALLED DUE TO
SITE ERROR. SITE STAFF
INSTRUCTED TO COMPLETE
REGULAR SAFETY CALLS
ALONGSIDE OPEN LABEL
PHASE

US3412304

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 08:11
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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.

US3412304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	08:31 (24 HR)
Collection date and time (derived)	25 MAR 2021 08:31

US3412304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

Date of Contact	05 NOV 2020
Time of Contact	11:00
Date and Time of Contact (derived)	05 NOV 2020 11:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	37.1 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

324 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

325 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

Date	06 NOV 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	97.5 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

328 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

Date	08 NOV 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

340 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	92 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

Date	11 NOV 2020
------	-------------

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

O2 Saturation	94 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

348 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

352 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	100.6 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 type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

356 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

360 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

361 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

364 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

365 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 NOV 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

380 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

384 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

388 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

396 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.9 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

400 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

404 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input checked="" 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input checked="" 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 NOV 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

420 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input 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 checked="" 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.5 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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

425 of 2984

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 14:43:01

Generated On: 11 Aug 2021 22:38:27

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"/>

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

Date of Visit	05 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	05 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 05:37:51

Generated On: 11 Aug 2021 22:38:27

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 07 NOV 2020

End Date 19 NOV 2020

Oxygen Saturation 92 %

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 _____

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 05:37:51

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 28 Apr 2021 05:37:51

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:31

Generated On: 11 Aug 2021 22:38:27

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	07 NOV 2020
Day 5	Yes	24 NOV 2020
Day 7	Yes	11 NOV 2020
Day 9	Yes	13 NOV 2020
Day 14	Yes	18 NOV 2020
Day 21	Yes	25 NOV 2020
Day 28	Yes	3 DEC 2020

US3412304

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 11:05
Height (xxx.x)	174 cm
Weight (xxx.x)	109 kg
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412304

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3412304

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 18:18:32

Generated On: 11 Aug 2021 22:38:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

5 NOV 2020

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 DEC 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	3 DEC 2020 09:10
Height (xxx.x)	177.5 cm
Weight (xxx.x)	109.9 kg
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:30

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 DEC 2020

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

US3412304

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 18:18:30

Generated On: 11 Aug 2021 22:38:27

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

3 DEC 2020

US3412304

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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

Visit date (dd MMM yyyy)	18 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
------------	---------------

US3412304

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 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>)	18 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

US3412304

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Height	174.7 cm
Weight	107.8 kg
BMI (xxx.x)	35.32100

US3412304

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Height	174.7 cm
Weight	107.8 kg
BMI (xxx.x)	35.32100
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	9:15 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 9:15
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Height	174.7 cm
Weight	107.8 kg
BMI (xxx.x)	35.32100
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	9:59 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 9:59
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3412304

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 9:30 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 9:30

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

US3412304

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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

Collection date (dd MMM yyyy)	18 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	8:25 (24 HR)
-------------------------------	--------------

Collection date and time (derived)	18 JAN 2021 8:25
------------------------------------	------------------

US3412304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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

Collection date (dd MMM yyyy)	18 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	8:37
---------------------------------	------

Collection Date and Time (derived)	18 JAN 2021 8:37
------------------------------------	------------------

US3412304

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	07:21 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 07:21
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 FEB 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 08:52
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412304

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3412304

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

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) 25 FEB 2021

What was the treatment time? (00:00-23:59) 08:21 (24 HR)

Treatment Date and Time (derived) 25 FEB 2021 08:21

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

US3412304

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 18:18:32

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:41:24

Generated On: 11 Aug 2021 22:38:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412304

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	08:11 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 08:11
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412304

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

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.

US3412304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 MAR 2021
Collection time (00:00-23:59)	08:31 (24 HR)
Collection date and time (derived)	25 MAR 2021 08:31

US3412304

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:40:58

Generated On: 11 Aug 2021 22:38:27

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:57

Generated On: 11 Aug 2021 22:38:27

AEID	USA-US061-2020-MRNA-1273-P30 1000009
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)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 NOV 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

466 of 2984

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:57

Generated On: 11 Aug 2021 22:38:27

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:40:57

Generated On: 11 Aug 2021 22:38:27

SUBJECT REPORTS ON
03-NOV-2020 HE STARTED
FEELING FATIGUED AND
FEVERISH TEMP WAS 99.9F.
REPORTS BODY ACHES SINCE
THEN. TEMP WAS 100.1 LAST
EVENING (04-NOV-20), NO
OTHER SYMPTOMS. DENIED
N/V, SDB, COUGH, NOT AWARE
OF BEING AROUND ANY ONE
WITH POSTIVE COVID. SUBJECT
PRESENTED FOR SICK VISIT ON
05-NOV-2020 AND HAD SIGNS
AND SYMPTOMS UNTIL
28-NOV-2020. SUBJECT
PRESENTED FOR DAY 28
CONVALESCENT PERIOD ON
03-DEC-2020. SUBJECT ONLY
TOOK TUSSIN DM AND
PSEUDOPHED FOR SYMPTOMS
OF COVID.

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)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:44:27

Generated On: 11 Aug 2021 22:38:27

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication ALTACE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

470 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 81

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

472 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication GLUCOSOMINE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS - LEFT FOOT
AND LOWER BACK

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)

474 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2012
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"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication GLUCOVANCE

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA

Dose per administration 500/5

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)

476 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication MOBIC

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

478 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

480 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2014
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

482 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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 2014	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication CRESTOR

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

484 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication OZEMPIC

Prophylaxis Yes ☐
No ☒

Indication TYPE TWO DIABETES

Dose per administration .25

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☒
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

486 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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)	8 SEP 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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLACTIC

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify INJECTION

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

488 of 2984

EAB) (1725)

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication TUSSIN DM

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 10

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

490 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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)		13 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 NOV 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

Name of Medication SUDAFED (PSEUDOEPHEDRINE HCL)

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

TWICE DAILY AS NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 14:26:22

Generated On: 11 Aug 2021 22:38:27

	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)	16 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:44:27

Generated On: 11 Aug 2021 22:38:27

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412304

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:38:27

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

US3412304

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:38:27

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 ☐

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 21:52
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

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5
Date of submission (Pre-filled from custom function)	18/NOV/2020 17:16
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

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 19:35
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

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5
Date of submission (Pre-filled from custom function)	02/DEC/2020 03:41
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

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 18:18:33

Generated On: 11 Aug 2021 22:38:27

SAEID	USA-US061-2020-MRNA-1273-P301000009
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)	5
Date of submission (Pre-filled from custom function)	14/DEC/2020 10:12
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

US3412304 (Prod: New Horizons Clinical Research)

US3412304

Form: Participant Creation

Generated On: 11 Aug 2021 22:38:27

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'US3412304'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:19:59

US3412304

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 14:17:53

US3412304

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:20:01

US3412304

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	24 Aug 2020 14:17:53

US3412304

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'SCRN'	System	24 Aug 2020 14:17:53

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered (b) (6) 1950'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:20:02

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '70'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'YEARS'	System	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '70'	System	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Sep 2020 12:29:15
Query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' answered with 'subject is male ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:03:46
User entered 'Male (M)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:03:31
User opened query 'Per CDM, The sex is 'Female'. However Childbearing potential page has not filled. Please complete the page' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 04:06:14
User entered 'Female (F)'	Steven Anderson (b) (4) (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'I'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:38:27

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Steven Anderson (b) (4)	24 Aug 2020 14:18:08

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Aug 2020'	System	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2020'	System	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Amendment 2 (2)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:30

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 13:20:01

US3412304

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:38:27

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'I'	System	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:38:27

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:38:27

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:07:19

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Seafood allergy - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 20:17:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 20:17:49
Data point term sent to Coder	System	02 Sep 2020 19:53:32
User entered 'allergic rhinitis - shrimp'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'un UNK 1955'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 1955'	System	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '1955'	System	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:53:16

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
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)	02 Sep 2020 19:55:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:55:49
Data point term sent to Coder	System	02 Sep 2020 19:54:35
User entered 'hyperlipidemia'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'un UNK 2010'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2010'	System	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2010'	System	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:53:43

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:55:48
Data point term sent to Coder	System	02 Sep 2020 19:54:35
User entered 'hypertension'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'un UNK 2012'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2012'	System	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2012'	System	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:54:07

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:55:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:55:48
Data point term sent to Coder	System	02 Sep 2020 19:54:35
User entered 'GERD'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'UN UNK 2010'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2010'	System	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2010'	System	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:54:26

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:54:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:54:04
DataPoint Verified.	(b) (4), (b) (6)	25 Oct 2020 22:56:30
User closed query 'Please correct spelling of foot' (Site from CRA).		25 Oct 2020 22:56:27
Query 'Please correct spelling of foot' answered with 'CORRECTED' (Site from CRA).	Melissa Fuson (b) (4)	28 Sep 2020 15:14:03
Data point term sent to Coder	System	28 Sep 2020 15:14:02
Coding entries removed.	Melissa Fuson (b) (4)	28 Sep 2020 15:13:55
User entered 'OSTEOARTHRITIS - LEFT FOOT AND LOWER BACK' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:13:55
User opened query 'Please correct spelling of foot' (Site from CRA).	(b) (4), (b) (6)	26 Sep 2020 12:48:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 06:41:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Sep 2020 06:41:53
Data point term sent to Coder	System	02 Sep 2020 19:55:39
User entered 'osteoarthritis - left food and lower back'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'un UNK 2012'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2012'	System	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2012'	System	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:55:16

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:57:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Sep 2020 19:57:53
Data point term sent to Coder	System	02 Sep 2020 19:56:43
User entered 'hyperglycemia'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'un UNK 2010'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2010'	System	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2010'	System	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	02 Sep 2020 19:55:43

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:15:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 19:15:25
Data point term sent to Coder	System	19 Oct 2020 19:14:07
User entered 'DIABETES - TYPE II'	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'UN UNK 2000'	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 20:14:57
User entered 'Yes (Y)' reason for change: Data Entry Error	System	19 Oct 2020 20:14:57
User opened query 'Data is required. Please complete.' (Site from System).	Steven Anderson (b) (4)	19 Oct 2020 20:14:57
User entered empty.	(b) (4)	
DataPoint activated with code reason code Data required.	System	19 Oct 2020 19:13:26
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
	(b) (4)	
	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
	(b) (4)	
	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04
	(b) (4)	

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Melissa Fuson (b) (4)	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'Jan 2000'	System	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '2000'	System	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:38:27

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered empty.	System	19 Oct 2020 19:13:26
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	19 Oct 2020 19:10:29
DataPoint inactivated with code reason code Data not required.	Jacob sekinger (b) (4)	02 Sep 2020 19:56:04

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '9:25'	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '24 Aug 2020 9:25'	System	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '174.7' cm	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09
DataPoint set to visible.	System	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '110.4' kg	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09
DataPoint set to visible.	System	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '36.17289'	System	02 Sep 2020 19:58:09
DataPoint set to visible.	System	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'kg/m2'	System	02 Sep 2020 19:58:09
DataPoint set to visible.	System	24 Aug 2020 14:18:35

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'bpm'	System	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'breaths/min'	System	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'mmHg'	System	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'mmHg'	System	02 Sep 2020 19:58:09

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34

US3412304

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34

US3412304

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 19:58:45

US3412304

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 19:58:45

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'retired, some interactions with others. does shopping and dining out.'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'I'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:38:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 20:05:39

US3412304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:49

US3412304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Steven Anderson (b) (4)	24 Aug 2020 14:18:49

US3412304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	24 Aug 2020 14:18:49

US3412304

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'VISIT1'	System	24 Aug 2020 14:18:49

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:14:49

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '187249'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:14:49

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	24 Aug 2020 14:14:49

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:22:47

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:22:47

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:22:47

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:22:47

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	24 Aug 2020 14:22:47

US3412304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:38:27

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Please complete field' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:25:11
Query 'Please complete field' answered with 'COMPLETED FIELD' (Site from CRA).	Melissa Fuson (b) (4)	28 Sep 2020 15:50:34
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	28 Sep 2020 15:49:43
User opened query 'Please complete field' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:50:30
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:25:15

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '09:25'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '24 Aug 2020 09:25'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '36.8' C	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '74'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'bpm'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '17'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'breaths/min'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '120'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '70'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered missing code ND - Not Done.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '10:56'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '24 Aug 2020 10:56'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '98.0' F	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '66'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'bpm'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '14'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'breaths/min'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '120'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '66'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	02 Sep 2020 20:08:33

US3412304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:10:52
User closed query 'Please update to no -per CRF completion guidelines since screening and Day 1 are same day and already entered at screening' (Site from CRA).		23 Oct 2020 16:10:50
Query 'Please update to no -per CRF completion guidelines since screening and Day 1 are same day and already entered at screening' answered with 'UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:52:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:52:06
User opened query 'Please update to no -per CRF completion guidelines since screening and Day 1 are same day and already entered at screening' (Site from CRA).	(b) (4), (b) (6)	26 Sep 2020 12:53:39
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:08:48

US3412304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 16:10:52
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:52:06
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 20:08:48

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '10:25'	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '24 Aug 2020 10:25'	System	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'ONCE'	System	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 14:33:03

US3412304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:16

US3412304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:16

US3412304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '9:59'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:16

US3412304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '24 Aug 2020 9:59'	System	02 Sep 2020 20:10:16

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '24 Aug 2020'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '10:03'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '24 Aug 2020 10:03'	System	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Jacob sekinger (b) (4)	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	02 Sep 2020 20:10:53

US3412304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:08:47

US3412304

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	31 Aug 2020 18:08:47

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:03:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b67183f0-e6ec-45c0-96df-6b29aeec3696'	System	24 Aug 2020 15:03:50
User entered 'Yes (Y)'	System	24 Aug 2020 15:03:50

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:03:16', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b67183f0-e6ec-45c0-96df-6b29aeec3696'	System	24 Aug 2020 15:03:50
User entered '98.0'	System	24 Aug 2020 15:03:50

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:03:23', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b67183f0-e6ec-45c0-96df-6b29aeec3696'	System	24 Aug 2020 15:03:50
User entered 'No (N)'	System	24 Aug 2020 15:03:50

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:03:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b67183f0-e6ec-45c0-96df-6b29aeec3696'	System	24 Aug 2020 15:03:50
User entered '24 Aug 2020 11:03'	System	24 Aug 2020 15:03:50

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 10:45'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 13:15'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:30:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '02158b89-7177-4960-a896-9741f03dc242'	System	25 Aug 2020 00:31:11
User entered 'Yes (Y)'	System	25 Aug 2020 00:31:11

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:30:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '02158b89-7177-4960-a896-9741f03dc242'	System	25 Aug 2020 00:31:11
User entered '98.4'	System	25 Aug 2020 00:31:11

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:30:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '02158b89-7177-4960-a896-9741f03dc242'	System	25 Aug 2020 00:31:11
User entered 'No (N)'	System	25 Aug 2020 00:31:11

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:08', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '02158b89-7177-4960-a896-9741f03dc242'	System	25 Aug 2020 00:31:11
User entered '24 Aug 2020 20:31'	System	25 Aug 2020 00:31:11

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 14:10'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 2'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3bd08504-f81d-419c-b6e9-5da44619ab44' User entered 'Yes (Y)'	System	26 Aug 2020 00:39:48
	System	26 Aug 2020 00:39:48

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:36', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3bd08504-f81d-419c-b6e9-5da44619ab44' User entered '97.8'	System	26 Aug 2020 00:39:48
	System	26 Aug 2020 00:39:48

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3bd08504-f81d-419c-b6e9-5da44619ab44'	System	26 Aug 2020 00:39:48
User entered 'No (N)'	System	26 Aug 2020 00:39:48

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:46', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3bd08504-f81d-419c-b6e9-5da44619ab44' User entered '25 Aug 2020 20:39'	System	26 Aug 2020 00:39:48
	System	26 Aug 2020 00:39:48

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 3'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:33:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5f9080e-fa2c-45f1-b75f-3994bf5243bc' User entered 'Yes (Y)'	System	27 Aug 2020 00:33:47
	System	27 Aug 2020 00:33:47

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:33:38', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5f9080e-fa2c-45f1-b75f-3994bf5243bc' User entered '97.9'	System	27 Aug 2020 00:33:47
	System	27 Aug 2020 00:33:47

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:33:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5f9080e-fa2c-45f1-b75f-3994bf5243bc'	System	27 Aug 2020 00:33:47
User entered 'No (N)'	System	27 Aug 2020 00:33:47

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:33:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5f9080e-fa2c-45f1-b75f-3994bf5243bc' User entered '26 Aug 2020 20:33'	System	27 Aug 2020 00:33:47
	System	27 Aug 2020 00:33:47

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 4'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:14', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2ace1081-403c-434c-af63-452865c27c07' User entered 'Yes (Y)'	System	28 Aug 2020 01:34:29
	System	28 Aug 2020 01:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2ace1081-403c-434c-af63-452865c27c07'	System	28 Aug 2020 01:34:29
User entered '96.8'	System	28 Aug 2020 01:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2ace1081-403c-434c-af63-452865c27c07'	System	28 Aug 2020 01:34:29
User entered 'No (N)'	System	28 Aug 2020 01:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2ace1081-403c-434c-af63-452865c27c07'	System	28 Aug 2020 01:34:29
User entered '27 Aug 2020 21:34'	System	28 Aug 2020 01:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 5'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '07ba87aa-9586-4237-938b-6fae248cde52'	System	29 Aug 2020 00:32:55
User entered 'Yes (Y)'	System	29 Aug 2020 00:32:55

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '07ba87aa-9586-4237-938b-6fae248cde52' User entered '97.7'	System	29 Aug 2020 00:32:55
	System	29 Aug 2020 00:32:55

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '07ba87aa-9586-4237-938b-6fae248cde52'	System	29 Aug 2020 00:32:55
User entered 'No (N)'	System	29 Aug 2020 00:32:55

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '07ba87aa-9586-4237-938b-6fae248cde52'	System	29 Aug 2020 00:32:55
User entered '28 Aug 2020 20:32'	System	29 Aug 2020 00:32:55

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 6'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:39:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '559aede3-02a5-4395-bc3c-ac8d622ef4e8' User entered 'Yes (Y)'	System	29 Aug 2020 23:40:10
	System	29 Aug 2020 23:40:10

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:03', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '559aede3-02a5-4395-bc3c-ac8d622ef4e8' User entered '97.5'	System	29 Aug 2020 23:40:10
	System	29 Aug 2020 23:40:10

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:05', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '559aede3-02a5-4395-bc3c-ac8d622ef4e8'	System	29 Aug 2020 23:40:10
User entered 'No (N)'	System	29 Aug 2020 23:40:10

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:09', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '559aede3-02a5-4395-bc3c-ac8d622ef4e8'	System	29 Aug 2020 23:40:10
User entered '29 Aug 2020 19:40'	System	29 Aug 2020 23:40:10

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 7'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:18:49', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '56bf73ad-3e26-4bbd-bf9b-11472a631c2d' User entered 'Yes (Y)'	System	31 Aug 2020 00:19:04
	System	31 Aug 2020 00:19:04

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:18:56', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '56bf73ad-3e26-4bbd-bf9b-11472a631c2d' User entered '98.0'	System	31 Aug 2020 00:19:04
	System	31 Aug 2020 00:19:04

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:18:58', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '56bf73ad-3e26-4bbd-bf9b-11472a631c2d'	System	31 Aug 2020 00:19:04
User entered 'No (N)'	System	31 Aug 2020 00:19:04

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '56bf73ad-3e26-4bbd-bf9b-11472a631c2d' User entered '30 Aug 2020 20:19'	System	31 Aug 2020 00:19:04
	System	31 Aug 2020 00:19:04

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ab4d92f9-6084-44f8-ba57-e1d3fad36b9d' User entered 'None (1)'	System	24 Aug 2020 15:04:42
	System	24 Aug 2020 15:04:42

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:24', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ab4d92f9-6084-44f8-ba57-e1d3fad36b9d'	System	24 Aug 2020 15:04:42
User entered 'No (N)'	System	24 Aug 2020 15:04:42

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ab4d92f9-6084-44f8-ba57-e1d3fad36b9d' User entered 'No (N)'	System	24 Aug 2020 15:04:42
	System	24 Aug 2020 15:04:42

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ab4d92f9-6084-44f8-ba57-e1d3fad36b9d' User entered 'None (1)'	System	24 Aug 2020 15:04:42
	System	24 Aug 2020 15:04:42

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ab4d92f9-6084-44f8-ba57-e1d3fad36b9d' User entered '24 Aug 2020 11:04'	System	24 Aug 2020 15:04:42
	System	24 Aug 2020 15:04:42

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 10:45'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 13:15'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0046ae9d-241e-4929-967d-de802843bb11' User entered 'None (1)'	System	25 Aug 2020 00:32:00
	System	25 Aug 2020 00:32:00

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0046ae9d-241e-4929-967d-de802843bb11'	System	25 Aug 2020 00:32:00
User entered 'No (N)'	System	25 Aug 2020 00:32:00

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0046ae9d-241e-4929-967d-de802843bb11' User entered 'No (N)'	System	25 Aug 2020 00:32:00
	System	25 Aug 2020 00:32:00

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:53', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0046ae9d-241e-4929-967d-de802843bb11' User entered 'None (1)'	System	25 Aug 2020 00:32:00
	System	25 Aug 2020 00:32:00

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:31:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0046ae9d-241e-4929-967d-de802843bb11'	System	25 Aug 2020 00:32:00
User entered '24 Aug 2020 20:31'	System	25 Aug 2020 00:32:00

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 14:10'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 2'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:56', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'cd3b75e6-12c7-4339-8e51-d0fc8bb93676' User entered 'None (1)'	System	26 Aug 2020 00:40:13
	System	26 Aug 2020 00:40:13

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:39:59', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'cd3b75e6-12c7-4339-8e51-d0fc8bb93676' User entered 'No (N)'	System	26 Aug 2020 00:40:13
	System	26 Aug 2020 00:40:13

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'cd3b75e6-12c7-4339-8e51-d0fc8bb93676' User entered 'No (N)'	System	26 Aug 2020 00:40:13
	System	26 Aug 2020 00:40:13

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:05', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'cd3b75e6-12c7-4339-8e51-d0fc8bb93676' User entered 'None (1)'	System	26 Aug 2020 00:40:13
	System	26 Aug 2020 00:40:13

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'cd3b75e6-12c7-4339-8e51-d0fc8bb93676'	System	26 Aug 2020 00:40:13
User entered '25 Aug 2020 20:40'	System	26 Aug 2020 00:40:13

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 3'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:03', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '4583113d-2947-40cb-afee-3caa36744dc5' User entered 'None (1)'	System	27 Aug 2020 00:34:29
	System	27 Aug 2020 00:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:06', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '4583113d-2947-40cb-afee-3caa36744dc5' User entered 'No (N)'	System	27 Aug 2020 00:34:29
	System	27 Aug 2020 00:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:11', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '4583113d-2947-40cb-afee-3caa36744dc5' User entered 'No (N)'	System	27 Aug 2020 00:34:29
	System	27 Aug 2020 00:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '4583113d-2947-40cb-afee-3caa36744dc5' User entered 'None (1)'	System	27 Aug 2020 00:34:29
	System	27 Aug 2020 00:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '4583113d-2947-40cb-afee-3caa36744dc5' User entered '26 Aug 2020 20:34'	System	27 Aug 2020 00:34:29
	System	27 Aug 2020 00:34:29

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 4'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:28', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '962e1498-c1d9-4b3e-8340-f56dcf9f8923'	System	28 Aug 2020 01:34:44
User entered 'None (1)'	System	28 Aug 2020 01:34:44

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '962e1498-c1d9-4b3e-8340-f56dcf9f8923'	System	28 Aug 2020 01:34:44
User entered 'No (N)'	System	28 Aug 2020 01:34:44

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:36', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '962e1498-c1d9-4b3e-8340-f56dcf9f8923' User entered 'No (N)'	System	28 Aug 2020 01:34:44
	System	28 Aug 2020 01:34:44

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:38', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '962e1498-c1d9-4b3e-8340-f56dcf9f8923' User entered 'None (1)'	System	28 Aug 2020 01:34:44
	System	28 Aug 2020 01:34:44

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '962e1498-c1d9-4b3e-8340-f56dcf9f8923' User entered '27 Aug 2020 21:34'	System	28 Aug 2020 01:34:44
	System	28 Aug 2020 01:34:44

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 5'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:55', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5e80ddd-4bab-43aa-9ed9-8381941324e0' User entered 'None (1)'	System	29 Aug 2020 00:33:10
	System	29 Aug 2020 00:33:10

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:32:59', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5e80ddd-4bab-43aa-9ed9-8381941324e0' User entered 'No (N)'	System	29 Aug 2020 00:33:10
	System	29 Aug 2020 00:33:10

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5e80ddd-4bab-43aa-9ed9-8381941324e0' User entered 'No (N)'	System	29 Aug 2020 00:33:10
	System	29 Aug 2020 00:33:10

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:03', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5e80ddd-4bab-43aa-9ed9-8381941324e0' User entered 'None (1)'	System	29 Aug 2020 00:33:10
	System	29 Aug 2020 00:33:10

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:06', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5e80ddd-4bab-43aa-9ed9-8381941324e0' User entered '28 Aug 2020 20:33'	System	29 Aug 2020 00:33:10
	System	29 Aug 2020 00:33:10

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 6'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8018cbe8-0d39-4cc6-b86c-7a0546ff06e5' User entered 'None (1)'	System	29 Aug 2020 23:40:30
	System	29 Aug 2020 23:40:30

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:16', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8018cbe8-0d39-4cc6-b86c-7a0546ff06e5'	System	29 Aug 2020 23:40:30
User entered 'No (N)'	System	29 Aug 2020 23:40:30

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8018cbe8-0d39-4cc6-b86c-7a0546ff06e5'	System	29 Aug 2020 23:40:30
User entered 'No (N)'	System	29 Aug 2020 23:40:30

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8018cbe8-0d39-4cc6-b86c-7a0546ff06e5' User entered 'None (1)'	System	29 Aug 2020 23:40:30
	System	29 Aug 2020 23:40:30

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:28', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8018cbe8-0d39-4cc6-b86c-7a0546ff06e5' User entered '29 Aug 2020 19:40'	System	29 Aug 2020 23:40:30
	System	29 Aug 2020 23:40:30

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 7'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:05', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '084912e4-e4fd-40fe-85be-b59bf3834f2d' User entered 'None (1)'	System	31 Aug 2020 00:19:21
	System	31 Aug 2020 00:19:21

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:07', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '084912e4-e4fd-40fe-85be-b59bf3834f2d'	System	31 Aug 2020 00:19:21
User entered 'No (N)'	System	31 Aug 2020 00:19:21

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '084912e4-e4fd-40fe-85be-b59bf3834f2d' User entered 'No (N)'	System	31 Aug 2020 00:19:21
	System	31 Aug 2020 00:19:21

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:15', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '084912e4-e4fd-40fe-85be-b59bf3834f2d' User entered 'None (1)'	System	31 Aug 2020 00:19:21
	System	31 Aug 2020 00:19:21

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:17', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '084912e4-e4fd-40fe-85be-b59bf3834f2d' User entered '30 Aug 2020 20:19'	System	31 Aug 2020 00:19:21
	System	31 Aug 2020 00:19:21

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:04:59', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:05:02', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:05:04', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'None (0)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:05:09', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered 'No (N)'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T11:05:15', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c33fdad0-bcd9-4e20-8ccd-5ad344e43626' User entered '24 Aug 2020 11:05'	System	24 Aug 2020 15:05:16
	System	24 Aug 2020 15:05:16

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 10:45'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 13:15'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:07', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35' User entered 'None (0)'	System	25 Aug 2020 00:32:43
	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35' User entered 'None (0)'	System	25 Aug 2020 00:32:43
	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35'	System	25 Aug 2020 00:32:43
User entered 'None (0)'	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:24', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35' User entered 'None (0)'	System	25 Aug 2020 00:32:43
	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35'	System	25 Aug 2020 00:32:43
User entered 'None (0)'	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:28', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35'	System	25 Aug 2020 00:32:43
User entered 'None (0)'	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35' User entered 'No (N)'	System	25 Aug 2020 00:32:43
	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-24T20:32:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '0c16e767-e8a1-4bb9-9cc7-3e3aba9dad35'	System	25 Aug 2020 00:32:43
User entered '24 Aug 2020 20:32'	System	25 Aug 2020 00:32:43

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Aug 2020 14:10'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 2'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:15', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'None (0)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered 'No (N)'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-25T20:40:37', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1ebff6a1-85a1-4d03-8457-4ec46a7ae844'	System	26 Aug 2020 00:40:40
User entered '25 Aug 2020 20:40'	System	26 Aug 2020 00:40:40

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 3'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114' User entered 'None (0)'	System	27 Aug 2020 00:34:55
	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:38', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114' User entered 'None (0)'	System	27 Aug 2020 00:34:55
	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114'	System	27 Aug 2020 00:34:55
User entered 'None (0)'	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:42', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114'	System	27 Aug 2020 00:34:55
User entered 'None (0)'	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114'	System	27 Aug 2020 00:34:55
User entered 'None (0)'	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:47', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114' User entered 'None (0)'	System	27 Aug 2020 00:34:55
	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:51', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114'	System	27 Aug 2020 00:34:55
User entered 'No (N)'	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-26T20:34:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a83c9883-fdf7-4edd-a723-f8c3bf923114'	System	27 Aug 2020 00:34:55
User entered '26 Aug 2020 20:34'	System	27 Aug 2020 00:34:55

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 4'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f'	System	28 Aug 2020 01:35:08
User entered 'None (0)'	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:46', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f' User entered 'None (0)'	System	28 Aug 2020 01:35:08
	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f'	System	28 Aug 2020 01:35:08
User entered 'None (0)'	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f' User entered 'None (0)'	System	28 Aug 2020 01:35:08
	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:52', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f'	System	28 Aug 2020 01:35:08
User entered 'None (0)'	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f' User entered 'None (0)'	System	28 Aug 2020 01:35:08
	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:34:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f'	System	28 Aug 2020 01:35:08
User entered 'No (N)'	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-27T21:35:02', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a2400516-9804-4958-a6ad-0607a43b767f' User entered '27 Aug 2020 21:35'	System	28 Aug 2020 01:35:08
	System	28 Aug 2020 01:35:08

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 5'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82' User entered 'None (0)'	System	29 Aug 2020 00:33:30
	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'None (0)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:14', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'None (0)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:16', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'None (0)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'None (0)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'None (0)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:24', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered 'No (N)'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-28T20:33:27', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3305c545-23ad-46c5-b5f3-c441dac90c82'	System	29 Aug 2020 00:33:30
User entered '28 Aug 2020 20:33'	System	29 Aug 2020 00:33:30

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 6'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:37', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered 'None (0)'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f'	System	29 Aug 2020 23:40:49
User entered 'No (N)'	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-29T19:40:47', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1e41a15f-8e59-42c3-8986-1e21e0add98f' User entered '29 Aug 2020 19:40'	System	29 Aug 2020 23:40:49
	System	29 Aug 2020 23:40:49

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 7'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:23', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:28', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'None (0)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered 'No (N)'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-08-30T20:19:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e972ac18-6260-45a8-90ae-d76492b0cc96' User entered '30 Aug 2020 20:19'	System	31 Aug 2020 00:19:38
	System	31 Aug 2020 00:19:38

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 14:33:03

US3412304

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:15:13

US3412304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:15:13

US3412304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:15:13

US3412304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:15:13

US3412304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 18:15:18

US3412304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	31 Aug 2020 18:15:18

US3412304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Sep 2020 15:25:35

US3412304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '8 Sep 2020'	Mason Urban (b) (4)	08 Sep 2020 15:25:35

US3412304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Sep 2020 15:25:35

US3412304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Mason Urban (b) (4)	08 Sep 2020 15:25:35

US3412304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Sep 2020 15:25:39

US3412304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	08 Sep 2020 15:25:39

US3412304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:43:26

US3412304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '14 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:43:26

US3412304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	21 Sep 2020 12:43:26

US3412304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:43:26

US3412304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:43:35

US3412304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	21 Sep 2020 12:43:35

US3412304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:43:54

US3412304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:43:54

US3412304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Home (Home)'	Steven Anderson (b) (4)	21 Sep 2020 12:43:54

US3412304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'VISIT2'	System	21 Sep 2020 12:43:54

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52
	(b) (4)	

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '08:05'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '21 Sep 2020 08:05'	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '36.8' C	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '76'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'bpm'	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '15'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'breaths/min'	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '100'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '62'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Sep 2020 15:57:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 15:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	21 Sep 2020 12:44:52
User entered empty.	System	21 Sep 2020 12:44:52
	Steven Anderson (b) (4)	21 Sep 2020 12:44:52
	(b) (4)	

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '09:23' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '21 Sep 2020 09:23'	System	28 Sep 2020 15:57:28
User entered empty.	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '97.5' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Oral (Oral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '60' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'bpm'	System	28 Sep 2020 15:57:28
User entered empty.	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '16' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'breaths/min'	System	28 Sep 2020 15:57:28
User entered empty.	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '106' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	28 Sep 2020 15:57:28
User entered empty.	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '70' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:57:28
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'mmHg'	System	28 Sep 2020 15:57:28
User entered empty.	System	21 Sep 2020 12:44:52

US3412304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:32:22
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:31:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:04

US3412304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:32:22
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:31:08
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:45:04

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '08:50'	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '21 Sep 2020 08:50'	System	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'ONCE'	System	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 12:55:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:30

US3412304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:45:30

US3412304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '08:24'	Steven Anderson (b) (4)	21 Sep 2020 12:45:30

US3412304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '21 Sep 2020 08:24'	System	21 Sep 2020 12:45:30

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '08:28'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '21 Sep 2020 08:28'	System	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 12:45:49

US3412304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 12:45:54

US3412304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	21 Sep 2020 12:45:54

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:24:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e6e81827-f5b9-4bce-88ab-d522643a990a' User entered 'Yes (Y)'	System	21 Sep 2020 13:25:06
	System	21 Sep 2020 13:25:06

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:24:49', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e6e81827-f5b9-4bce-88ab-d522643a990a' User entered '97.5'	System	21 Sep 2020 13:25:06
	System	21 Sep 2020 13:25:06

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:24:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e6e81827-f5b9-4bce-88ab-d522643a990a'	System	21 Sep 2020 13:25:06
User entered 'No (N)'	System	21 Sep 2020 13:25:06

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e6e81827-f5b9-4bce-88ab-d522643a990a'	System	21 Sep 2020 13:25:06
User entered '21 Sep 2020 09:25'	System	21 Sep 2020 13:25:06

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:02:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd508d762-9b98-4e83-805c-db8ccff5913b' User entered 'Yes (Y)'	System	22 Sep 2020 00:03:07
	System	22 Sep 2020 00:03:07

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:02:51', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd508d762-9b98-4e83-805c-db8ccff5913b' User entered '97.9'	System	22 Sep 2020 00:03:07
	System	22 Sep 2020 00:03:07

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:02:55', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd508d762-9b98-4e83-805c-db8ccff5913b'	System	22 Sep 2020 00:03:07
User entered 'No (N)'	System	22 Sep 2020 00:03:07

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd508d762-9b98-4e83-805c-db8ccff5913b' User entered '21 Sep 2020 20:03'	System	22 Sep 2020 00:03:07
	System	22 Sep 2020 00:03:07

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 2'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:27', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b189b241-e180-4e32-97cd-3e137bd10d9f' User entered 'Yes (Y)'	System	23 Sep 2020 00:02:43
	System	23 Sep 2020 00:02:43

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b189b241-e180-4e32-97cd-3e137bd10d9f' User entered '97.1'	System	23 Sep 2020 00:02:43
	System	23 Sep 2020 00:02:43

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:36', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b189b241-e180-4e32-97cd-3e137bd10d9f' User entered 'No (N)'	System	23 Sep 2020 00:02:43
	System	23 Sep 2020 00:02:43

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b189b241-e180-4e32-97cd-3e137bd10d9f'	System	23 Sep 2020 00:02:43
User entered '22 Sep 2020 20:02'	System	23 Sep 2020 00:02:43

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 3'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:05:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c7c95d97-15ef-47e0-ba67-dd933fe09e4f' User entered 'Yes (Y)'	System	24 Sep 2020 00:06:18
	System	24 Sep 2020 00:06:18

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:05:58', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c7c95d97-15ef-47e0-ba67-dd933fe09e4f' User entered '97.7'	System	24 Sep 2020 00:06:18
	System	24 Sep 2020 00:06:18

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:06:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c7c95d97-15ef-47e0-ba67-dd933fe09e4f' User entered 'No (N)'	System	24 Sep 2020 00:06:18
	System	24 Sep 2020 00:06:18

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:06:17', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c7c95d97-15ef-47e0-ba67-dd933fe09e4f' User entered '23 Sep 2020 20:06'	System	24 Sep 2020 00:06:18
	System	24 Sep 2020 00:06:18

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 4'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:28:53', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5ee5f364-9fc1-4c34-a656-665655499437' User entered 'Yes (Y)'	System	25 Sep 2020 00:29:29
	System	25 Sep 2020 00:29:29

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:28:56', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5ee5f364-9fc1-4c34-a656-665655499437' User entered '97.8'	System	25 Sep 2020 00:29:29
	System	25 Sep 2020 00:29:29

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5ee5f364-9fc1-4c34-a656-665655499437' User entered 'No (N)'	System	25 Sep 2020 00:29:29
	System	25 Sep 2020 00:29:29

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5ee5f364-9fc1-4c34-a656-665655499437'	System	25 Sep 2020 00:29:29
User entered '24 Sep 2020 20:29'	System	25 Sep 2020 00:29:29

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 5'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:14', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bfbd9ef0-5755-419b-bb20-c7e979e15041' User entered 'Yes (Y)'	System	26 Sep 2020 20:43:11
	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bfbd9ef0-5755-419b-bb20-c7e979e15041' User entered '97.6'	System	26 Sep 2020 20:43:11
	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bfbd9ef0-5755-419b-bb20-c7e979e15041'	System	26 Sep 2020 20:43:11
User entered 'No (N)'	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bfbd9ef0-5755-419b-bb20-c7e979e15041' User entered '25 Sep 2020 20:03'	System	26 Sep 2020 20:43:11
	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 6'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:08', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3b8a3ade-7e76-4b5d-bb67-de03d49eb35c' User entered 'Yes (Y)'	System	26 Sep 2020 20:44:20
	System	26 Sep 2020 20:44:20

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:11', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3b8a3ade-7e76-4b5d-bb67-de03d49eb35c' User entered '97.5'	System	26 Sep 2020 20:44:20
	System	26 Sep 2020 20:44:20

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:14', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3b8a3ade-7e76-4b5d-bb67-de03d49eb35c'	System	26 Sep 2020 20:44:20
User entered 'No (N)'	System	26 Sep 2020 20:44:20

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3b8a3ade-7e76-4b5d-bb67-de03d49eb35c'	System	26 Sep 2020 20:44:20
User entered '26 Sep 2020 16:44'	System	26 Sep 2020 20:44:20

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 7'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:04:58', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3d3b613e-0638-4e2a-a3fc-c2eb9c587a57' User entered 'Yes (Y)'	System	28 Sep 2020 00:05:16
	System	28 Sep 2020 00:05:16

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:03', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3d3b613e-0638-4e2a-a3fc-c2eb9c587a57' User entered '98.7'	System	28 Sep 2020 00:05:16
	System	28 Sep 2020 00:05:16

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:05', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3d3b613e-0638-4e2a-a3fc-c2eb9c587a57'	System	28 Sep 2020 00:05:16
User entered 'No (N)'	System	28 Sep 2020 00:05:16

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3d3b613e-0638-4e2a-a3fc-c2eb9c587a57'	System	28 Sep 2020 00:05:16
User entered '27 Sep 2020 20:05'	System	28 Sep 2020 00:05:16

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:08', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '9b38fb30-9b3c-4683-b774-69066c780fc2' User entered 'None (1)'	System	21 Sep 2020 13:25:25
	System	21 Sep 2020 13:25:25

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:11', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '9b38fb30-9b3c-4683-b774-69066c780fc2' User entered 'No (N)'	System	21 Sep 2020 13:25:25
	System	21 Sep 2020 13:25:25

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:14', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '9b38fb30-9b3c-4683-b774-69066c780fc2' User entered 'No (N)'	System	21 Sep 2020 13:25:25
	System	21 Sep 2020 13:25:25

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '9b38fb30-9b3c-4683-b774-69066c780fc2' User entered 'None (1)'	System	21 Sep 2020 13:25:25
	System	21 Sep 2020 13:25:25

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:23', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '9b38fb30-9b3c-4683-b774-69066c780fc2'	System	21 Sep 2020 13:25:25
User entered '21 Sep 2020 09:25'	System	21 Sep 2020 13:25:25

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:04', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '50ca9408-bd55-4eef-b918-caa3ac2cf246' User entered 'None (1)'	System	22 Sep 2020 00:03:23
	System	22 Sep 2020 00:03:23

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '50ca9408-bd55-4eef-b918-caa3ac2cf246'	System	22 Sep 2020 00:03:23
User entered 'No (N)'	System	22 Sep 2020 00:03:23

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '50ca9408-bd55-4eef-b918-caa3ac2cf246' User entered 'No (N)'	System	22 Sep 2020 00:03:23
	System	22 Sep 2020 00:03:23

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:15', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '50ca9408-bd55-4eef-b918-caa3ac2cf246' User entered 'None (1)'	System	22 Sep 2020 00:03:23
	System	22 Sep 2020 00:03:23

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '50ca9408-bd55-4eef-b918-caa3ac2cf246'	System	22 Sep 2020 00:03:23
User entered '21 Sep 2020 20:03'	System	22 Sep 2020 00:03:23

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 2'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5a16f5e-3436-4ac7-adde-2e1b222b2d83' User entered 'None (1)'	System	23 Sep 2020 00:03:04
	System	23 Sep 2020 00:03:04

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:52', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5a16f5e-3436-4ac7-adde-2e1b222b2d83' User entered 'No (N)'	System	23 Sep 2020 00:03:04
	System	23 Sep 2020 00:03:04

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:55', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5a16f5e-3436-4ac7-adde-2e1b222b2d83' User entered 'No (N)'	System	23 Sep 2020 00:03:04
	System	23 Sep 2020 00:03:04

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:02:58', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5a16f5e-3436-4ac7-adde-2e1b222b2d83' User entered 'None (1)'	System	23 Sep 2020 00:03:04
	System	23 Sep 2020 00:03:04

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b5a16f5e-3436-4ac7-adde-2e1b222b2d83'	System	23 Sep 2020 00:03:04
User entered '22 Sep 2020 20:03'	System	23 Sep 2020 00:03:04

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 3'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:06:38', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ea0b88f8-10c9-4b3d-8813-5959e129e458'	System	24 Sep 2020 00:07:15
User entered 'None (1)'	System	24 Sep 2020 00:07:15

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:04', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ea0b88f8-10c9-4b3d-8813-5959e129e458' User entered 'No (N)'	System	24 Sep 2020 00:07:15
	System	24 Sep 2020 00:07:15

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:06', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ea0b88f8-10c9-4b3d-8813-5959e129e458' User entered 'No (N)'	System	24 Sep 2020 00:07:15
	System	24 Sep 2020 00:07:15

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:10', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ea0b88f8-10c9-4b3d-8813-5959e129e458' User entered 'None (1)'	System	24 Sep 2020 00:07:15
	System	24 Sep 2020 00:07:15

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'ea0b88f8-10c9-4b3d-8813-5959e129e458'	System	24 Sep 2020 00:07:15
User entered '23 Sep 2020 20:07'	System	24 Sep 2020 00:07:15

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 4'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '12cee647-b9f1-435a-85f7-f455f3135741' User entered 'None (1)'	System	25 Sep 2020 00:29:51
	System	25 Sep 2020 00:29:51

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '12cee647-b9f1-435a-85f7-f455f3135741' User entered 'No (N)'	System	25 Sep 2020 00:29:51
	System	25 Sep 2020 00:29:51

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '12cee647-b9f1-435a-85f7-f455f3135741' User entered 'No (N)'	System	25 Sep 2020 00:29:51
	System	25 Sep 2020 00:29:51

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '12cee647-b9f1-435a-85f7-f455f3135741' User entered 'None (1)'	System	25 Sep 2020 00:29:51
	System	25 Sep 2020 00:29:51

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '12cee647-b9f1-435a-85f7-f455f3135741'	System	25 Sep 2020 00:29:51
User entered '24 Sep 2020 20:29'	System	25 Sep 2020 00:29:51

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 5'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b9a74c2f-f23a-49c4-9af6-dfdea41cba98'	System	26 Sep 2020 20:43:11
User entered 'None (1)'	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:31', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b9a74c2f-f23a-49c4-9af6-dfdea41cba98'	System	26 Sep 2020 20:43:11
User entered 'No (N)'	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b9a74c2f-f23a-49c4-9af6-dfdea41cba98' User entered 'No (N)'	System	26 Sep 2020 20:43:11
	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b9a74c2f-f23a-49c4-9af6-dfdea41cba98' User entered 'None (1)'	System	26 Sep 2020 20:43:11
	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:38', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b9a74c2f-f23a-49c4-9af6-dfdea41cba98'	System	26 Sep 2020 20:43:11
User entered '25 Sep 2020 20:03'	System	26 Sep 2020 20:43:11

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 6'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7eb8debe-cee6-4db8-9963-002a983cef71' User entered 'None (1)'	System	26 Sep 2020 20:44:41
	System	26 Sep 2020 20:44:41

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:31', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7eb8debe-cee6-4db8-9963-002a983cef71' User entered 'No (N)'	System	26 Sep 2020 20:44:41
	System	26 Sep 2020 20:44:41

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7eb8debe-cee6-4db8-9963-002a983cef71' User entered 'No (N)'	System	26 Sep 2020 20:44:41
	System	26 Sep 2020 20:44:41

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7eb8debe-cee6-4db8-9963-002a983cef71' User entered 'None (1)'	System	26 Sep 2020 20:44:41
	System	26 Sep 2020 20:44:41

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7eb8debe-cee6-4db8-9963-002a983cef71' User entered '26 Sep 2020 16:44'	System	26 Sep 2020 20:44:41
	System	26 Sep 2020 20:44:41

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 7'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7d9486cc-62bd-43f0-b3f2-386c9c264cac' User entered 'None (1)'	System	28 Sep 2020 00:05:33
	System	28 Sep 2020 00:05:33

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7d9486cc-62bd-43f0-b3f2-386c9c264cac'	System	28 Sep 2020 00:05:33
User entered 'No (N)'	System	28 Sep 2020 00:05:33

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:24', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7d9486cc-62bd-43f0-b3f2-386c9c264cac' User entered 'No (N)'	System	28 Sep 2020 00:05:33
	System	28 Sep 2020 00:05:33

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7d9486cc-62bd-43f0-b3f2-386c9c264cac' User entered 'None (1)'	System	28 Sep 2020 00:05:33
	System	28 Sep 2020 00:05:33

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '7d9486cc-62bd-43f0-b3f2-386c9c264cac'	System	28 Sep 2020 00:05:33
User entered '27 Sep 2020 20:05'	System	28 Sep 2020 00:05:33

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:28', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:37', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e' User entered 'None (0)'	System	21 Sep 2020 13:25:54
	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e'	System	21 Sep 2020 13:25:54
User entered 'No (N)'	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T09:25:51', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b4c7d553-f3d9-4b43-a7bc-5c1f44e1de2e'	System	21 Sep 2020 13:25:54
User entered '21 Sep 2020 09:25'	System	21 Sep 2020 13:25:54

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 09:10'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 11:40'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:23', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:27', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:32', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'None (0)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:36', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888' User entered 'No (N)'	System	22 Sep 2020 00:03:45
	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-21T20:03:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e8caabb6-b661-4a04-a0a8-6f2b02d55888'	System	22 Sep 2020 00:03:45
User entered '21 Sep 2020 20:03'	System	22 Sep 2020 00:03:45

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '21 Sep 2020 12:35'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 2'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:05', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775'	System	23 Sep 2020 00:03:24
User entered 'None (0)'	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:07', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775' User entered 'None (0)'	System	23 Sep 2020 00:03:24
	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:09', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775' User entered 'None (0)'	System	23 Sep 2020 00:03:24
	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:11', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775' User entered 'None (0)'	System	23 Sep 2020 00:03:24
	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775' User entered 'None (0)'	System	23 Sep 2020 00:03:24
	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:15', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775' User entered 'None (0)'	System	23 Sep 2020 00:03:24
	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775'	System	23 Sep 2020 00:03:24
User entered 'No (N)'	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-22T20:03:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2c172717-686c-4846-9502-98ff056cf775'	System	23 Sep 2020 00:03:24
User entered '22 Sep 2020 20:03'	System	23 Sep 2020 00:03:24

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 3'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:17', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250' User entered 'None (0)'	System	24 Sep 2020 00:07:37
	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250' User entered 'None (0)'	System	24 Sep 2020 00:07:37
	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250'	System	24 Sep 2020 00:07:37
User entered 'None (0)'	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:23', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250' User entered 'None (0)'	System	24 Sep 2020 00:07:37
	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250' User entered 'None (0)'	System	24 Sep 2020 00:07:37
	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:27', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250'	System	24 Sep 2020 00:07:37
User entered 'None (0)'	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250' User entered 'No (N)'	System	24 Sep 2020 00:07:37
	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-23T20:07:34', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'e0cd691d-501e-48a6-92ca-fbc8d5e1f250'	System	24 Sep 2020 00:07:37
User entered '23 Sep 2020 20:07'	System	24 Sep 2020 00:07:37

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 4'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:52', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:29:56', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:30:09', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:30:11', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:30:13', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'None (0)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:30:16', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered 'No (N)'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-24T20:30:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1eabd68c-e72b-4b7b-b550-cdbd6c02611c' User entered '24 Sep 2020 20:30'	System	25 Sep 2020 00:30:22
	System	25 Sep 2020 00:30:22

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 5'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:41', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:46', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862' User entered 'None (0)'	System	26 Sep 2020 20:43:12
	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862'	System	26 Sep 2020 20:43:12
User entered 'No (N)'	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-25T20:03:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '76e646f8-3f05-4aa4-9088-a2e8f83f4862'	System	26 Sep 2020 20:43:12
User entered '25 Sep 2020 20:03'	System	26 Sep 2020 20:43:12

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 6'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:46', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:48', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:50', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:52', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'None (0)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered 'No (N)'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-26T16:44:59', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cc73bc3-2b90-4684-a4bb-ad6d5a58cc5b' User entered '26 Sep 2020 16:44'	System	26 Sep 2020 20:45:02
	System	26 Sep 2020 20:45:02

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	21 Sep 2020 12:55:49
User entered 'Day 7'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:34', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:37', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:42', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'None (0)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered 'No (N)'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-09-27T20:05:47', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b21579b3-a0e6-4a61-b366-8f82e701984e' User entered '27 Sep 2020 20:05'	System	28 Sep 2020 00:05:50
	System	28 Sep 2020 00:05:50

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 12:55:49

US3412304

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:38:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 12:55:49

US3412304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:10:51

US3412304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Sep 2020 13:31:18
User entered '28 Sep 2020' reason for change: Data Entry Error	System	28 Sep 2020 13:31:18
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 13:31:18
User entered '04 Sep 2020'	(b) (4)	
	Steven Anderson (b) (4)	21 Sep 2020 13:10:51
	(b) (4)	

US3412304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	21 Sep 2020 13:10:51

US3412304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:10:51

US3412304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:11:08

US3412304

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	21 Sep 2020 13:11:08

US3412304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:11:26

US3412304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	05 Oct 2020 13:11:59
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	05 Oct 2020 13:11:59
User entered '5 Oct 2020' reason for change: Data Entry Error	Mason Urban (b) (4)	05 Oct 2020 13:11:59
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Sep 2020 13:11:26
User entered '11 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 13:11:26

US3412304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	21 Sep 2020 13:11:26

US3412304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:11:26

US3412304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:11:31

US3412304

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	21 Sep 2020 13:11:31

US3412304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:00

US3412304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	12 Oct 2020 14:31:07
answered by data change (Site from System).		
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	12 Oct 2020 14:31:07
User entered '12 Oct 2020' reason for change: Data Entry Error	Mason Urban (b) (4)	12 Oct 2020 14:31:07
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '18 Sep 2020'	System	21 Sep 2020 13:12:00
	Steven Anderson (b) (4)	21 Sep 2020 13:12:00
	(b) (4)	

US3412304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:00

US3412304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:00

US3412304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:05

US3412304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	21 Sep 2020 13:12:05

US3412304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:23

US3412304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	System	19 Oct 2020 12:28:32
answered by data change (Site from System).		
User entered '19 Oct 2020' reason for change: Data Entry Error	System	19 Oct 2020 12:28:32
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).		
User entered '21 Sep 2020'	Steven Anderson (b) (4)	19 Oct 2020 12:28:32
	(b) (4)	
	System	21 Sep 2020 13:12:23
	Steven Anderson (b) (4)	21 Sep 2020 13:12:23
	(b) (4)	

US3412304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:23

US3412304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'VISIT3'	System	21 Sep 2020 13:12:23

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty.	Steven Anderson (b) (4)	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered empty.	System	21 Sep 2020 13:12:32

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53

US3412304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53

US3412304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:33:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:12:59

US3412304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:33:01
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 12:28:47
User entered '19 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	19 Oct 2020 12:28:47
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	19 Oct 2020 12:28:32
User entered '21 Sep 2020'	Steven Anderson (b) (4)	21 Sep 2020 13:12:59

US3412304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:14:06

US3412304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 12:28:59
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 12:28:59
User entered '19 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	19 Oct 2020 12:28:59
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Oct 2020 12:28:32
User entered '21 Sep 2020'	System	19 Oct 2020 12:28:32
	Steven Anderson (b) (4)	21 Sep 2020 13:14:06
	(b) (4)	

US3412304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered '08:24' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Oct 2020 19:33:32
User entered '09:05'	Steven Anderson (b) (4)	21 Sep 2020 13:14:06

US3412304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '19 Oct 2020 08:24'	System	19 Oct 2020 19:33:32
User entered '19 Oct 2020 09:05'	System	19 Oct 2020 12:28:59
User entered '21 Sep 2020 09:05'	System	21 Sep 2020 13:14:06

US3412304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 12:22:07
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Sep 2020 13:14:10

US3412304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered '1'	System	21 Sep 2020 13:14:10

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 64'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-24T18:04:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '149bb9fe-ea32-47c4-b09f-68d702adb017'	System	24 Oct 2020 22:05:16
User entered 'No (N)'	System	24 Oct 2020 22:05:16

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-24T18:05:03', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '149bb9fe-ea32-47c4-b09f-68d702adb017'	System	24 Oct 2020 22:05:16
User entered 'No (N)'	System	24 Oct 2020 22:05:16

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-24T18:05:12', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '149bb9fe-ea32-47c4-b09f-68d702adb017' User entered '24 Oct 2020 18:05:12'	System	24 Oct 2020 22:05:16
	System	24 Oct 2020 22:05:16

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 71'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-31T17:29:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '37644210-6078-4ba8-a1ea-37846344fd2e' User entered 'No (N)'	System	31 Oct 2020 21:29:57
	System	31 Oct 2020 21:29:57

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-31T17:29:49', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '37644210-6078-4ba8-a1ea-37846344fd2e' User entered 'No (N)'	System	31 Oct 2020 21:29:57
	System	31 Oct 2020 21:29:57

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-10-31T17:29:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '37644210-6078-4ba8-a1ea-37846344fd2e' User entered '31 Oct 2020 17:29:54'	System	31 Oct 2020 21:29:57
	System	31 Oct 2020 21:29:57

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered 'Day 78'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:03:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered 'Yes (Y)'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:03:54', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea'	System	09 Nov 2020 03:04:55
User entered 'Yes (Y)'	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea'	System	09 Nov 2020 03:04:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:09', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered 'Yes (Y)'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '1'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:30', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '0'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:33', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea'	System	09 Nov 2020 03:04:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered 'No (N)'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-08T22:04:44', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'aa2a4fd1-7851-4e82-8f79-fd0a345386ea' User entered '08 Nov 2020 22:04:44'	System	09 Nov 2020 03:04:55
	System	09 Nov 2020 03:04:55

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 14:33:03

US3412304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:17:04
Data entry locked.	System	24 Aug 2020 14:33:03
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 14:33:03

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-21T17:00:46', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2015794e-1d59-4541-abac-71dd1a403511'	System	21 Nov 2020 22:01:06
User entered 'No (N)'	System	21 Nov 2020 22:01:06

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-21T17:00:55', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2015794e-1d59-4541-abac-71dd1a403511'	System	21 Nov 2020 22:01:06
User entered 'No (N)'	System	21 Nov 2020 22:01:06

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-21T17:00:59', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '2015794e-1d59-4541-abac-71dd1a403511' User entered '21 Nov 2020 17:00:59'	System	21 Nov 2020 22:01:06
	System	21 Nov 2020 22:01:06

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-26T21:44:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '637a078b-dd79-49b0-b55d-c7fd6c5d7150' User entered 'No (N)'	System	27 Nov 2020 02:44:31
	System	27 Nov 2020 02:44:31

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-26T21:44:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '637a078b-dd79-49b0-b55d-c7fd6c5d7150' User entered 'No (N)'	System	27 Nov 2020 02:44:31

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-11-26T21:44:29', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '637a078b-dd79-49b0-b55d-c7fd6c5d7150'	System	27 Nov 2020 02:44:31
User entered '26 Nov 2020 21:44:29'	System	27 Nov 2020 02:44:31

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-12T15:30:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '61020e69-8b9a-43a5-b866-07053c1310aa' User entered 'No (N)'	System	12 Dec 2020 20:30:59
	System	12 Dec 2020 20:30:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-12T15:30:53', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '61020e69-8b9a-43a5-b866-07053c1310aa' User entered 'No (N)'	System	12 Dec 2020 20:30:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-12T15:30:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '61020e69-8b9a-43a5-b866-07053c1310aa' User entered '12 Dec 2020 15:30:57'	System	12 Dec 2020 20:30:59
	System	12 Dec 2020 20:30:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-20T20:58:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1d955432-173b-459b-b833-feb789c8ebb7' User entered 'No (N)'	System	21 Dec 2020 01:58:47
	System	21 Dec 2020 01:58:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-20T20:58:39', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1d955432-173b-459b-b833-feb789c8ebb7'	System	21 Dec 2020 01:58:47
User entered 'No (N)'	System	21 Dec 2020 01:58:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-20T20:58:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '1d955432-173b-459b-b833-feb789c8ebb7' User entered '20 Dec 2020 20:58:45'	System	21 Dec 2020 01:58:47
	System	21 Dec 2020 01:58:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-26T20:30:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5780b6c-1def-48c3-a243-a8ea7a02580d' User entered 'No (N)'	System	27 Dec 2020 01:30:29
	System	27 Dec 2020 01:30:29

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-26T20:30:24', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5780b6c-1def-48c3-a243-a8ea7a02580d' User entered 'No (N)'	System	27 Dec 2020 01:30:29

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2020-12-26T20:30:27', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c5780b6c-1def-48c3-a243-a8ea7a02580d' User entered '26 Dec 2020 20:30:27'	System	27 Dec 2020 01:30:29
	System	27 Dec 2020 01:30:29

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-01T17:00:53', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c484e089-c8ca-4979-8971-dc0ab08ffd72'	System	01 Jan 2021 22:01:04
User entered 'No (N)'	System	01 Jan 2021 22:01:04

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-01T17:00:57', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c484e089-c8ca-4979-8971-dc0ab08ffd72'	System	01 Jan 2021 22:01:04
User entered 'No (N)'	System	01 Jan 2021 22:01:04

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-01T17:01:01', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c484e089-c8ca-4979-8971-dc0ab08ffd72' User entered '01 Jan 2021 17:01:01'	System	01 Jan 2021 22:01:04
	System	01 Jan 2021 22:01:04

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-09T09:39:43', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd12557f2-d210-4c25-a3b8-27d3f3cf5369' User entered 'No (N)'	System	09 Jan 2021 14:39:54
	System	09 Jan 2021 14:39:54

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-09T09:39:49', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd12557f2-d210-4c25-a3b8-27d3f3cf5369' User entered 'No (N)'	System	09 Jan 2021 14:39:54
	System	09 Jan 2021 14:39:54

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-09T09:39:52', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd12557f2-d210-4c25-a3b8-27d3f3cf5369' User entered '09 Jan 2021 09:39:52'	System	09 Jan 2021 14:39:54
	System	09 Jan 2021 14:39:54

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-16T17:00:35', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd3f08add-dc21-4a40-a876-07d7388da19d'	System	16 Jan 2021 22:00:43
User entered 'No (N)'	System	16 Jan 2021 22:00:43

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-16T17:00:37', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd3f08add-dc21-4a40-a876-07d7388da19d'	System	16 Jan 2021 22:00:43
User entered 'No (N)'	System	16 Jan 2021 22:00:43

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-16T17:00:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd3f08add-dc21-4a40-a876-07d7388da19d' User entered '16 Jan 2021 17:00:40'	System	16 Jan 2021 22:00:43
	System	16 Jan 2021 22:00:43

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-23T17:00:45', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cda3698-83ed-4ac7-9d3c-2308409ba03e' User entered 'No (N)'	System	23 Jan 2021 22:01:42
	System	23 Jan 2021 22:01:42

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-23T17:00:47', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cda3698-83ed-4ac7-9d3c-2308409ba03e' User entered 'No (N)'	System	23 Jan 2021 22:01:42

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-23T17:01:40', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '8cda3698-83ed-4ac7-9d3c-2308409ba03e' User entered '23 Jan 2021 17:01:40'	System	23 Jan 2021 22:01:42
	System	23 Jan 2021 22:01:42

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-30T19:48:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5f51e9f6-ad24-48d6-8d75-72ac7a5a9f44'	System	31 Jan 2021 00:48:30
User entered 'No (N)'	System	31 Jan 2021 00:48:30

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-30T19:48:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5f51e9f6-ad24-48d6-8d75-72ac7a5a9f44'	System	31 Jan 2021 00:48:30
User entered 'No (N)'	System	31 Jan 2021 00:48:30

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-01-30T19:48:26', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '5f51e9f6-ad24-48d6-8d75-72ac7a5a9f44'	System	31 Jan 2021 00:48:30
User entered '30 Jan 2021 19:48:26'	System	31 Jan 2021 00:48:30

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-06T11:11:19', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd7cf333a-d73a-4687-8f16-4b05d4749361' User entered 'No (N)'	System	06 Feb 2021 16:11:28
	System	06 Feb 2021 16:11:28

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-06T11:11:21', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd7cf333a-d73a-4687-8f16-4b05d4749361'	System	06 Feb 2021 16:11:28
User entered 'No (N)'	System	06 Feb 2021 16:11:28

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-06T11:11:25', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'd7cf333a-d73a-4687-8f16-4b05d4749361' User entered '06 Feb 2021 11:11:25'	System	06 Feb 2021 16:11:28
	System	06 Feb 2021 16:11:28

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-13T16:30:18', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b0f30733-22e1-4682-ac7e-6ee5fb8d2f89' User entered 'No (N)'	System	13 Feb 2021 21:30:26
	System	13 Feb 2021 21:30:26

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-13T16:30:20', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b0f30733-22e1-4682-ac7e-6ee5fb8d2f89'	System	13 Feb 2021 21:30:26
User entered 'No (N)'	System	13 Feb 2021 21:30:26

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-13T16:30:22', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b0f30733-22e1-4682-ac7e-6ee5fb8d2f89' User entered '13 Feb 2021 16:30:22'	System	13 Feb 2021 21:30:26
	System	13 Feb 2021 21:30:26

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-27T11:39:42-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b7a8f091-8c0c-4409-862c-7e5064580f2c'	System	27 Feb 2021 16:39:55
User entered 'No (N)'	System	27 Feb 2021 16:39:55

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-27T11:39:45-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b7a8f091-8c0c-4409-862c-7e5064580f2c'	System	27 Feb 2021 16:39:55
User entered 'No (N)'	System	27 Feb 2021 16:39:55

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-02-27T11:39:52-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'b7a8f091-8c0c-4409-862c-7e5064580f2c' User entered '27 Feb 2021 16:39:52'	System	27 Feb 2021 16:39:55
	System	27 Feb 2021 16:39:55

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-06T19:22:50-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '14b4a71b-ef34-4247-8563-d49f7930e5bb'	System	07 Mar 2021 00:22:59
User entered 'No (N)'	System	07 Mar 2021 00:22:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-06T19:22:52-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '14b4a71b-ef34-4247-8563-d49f7930e5bb'	System	07 Mar 2021 00:22:59
User entered 'No (N)'	System	07 Mar 2021 00:22:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-06T19:22:57-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '14b4a71b-ef34-4247-8563-d49f7930e5bb' User entered '06 Mar 2021 19:22:57'	System	07 Mar 2021 00:22:59
	System	07 Mar 2021 00:22:59

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-21T10:00:28-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '75c3d2aa-e68c-460e-ad87-a0f1c83439df'	System	21 Mar 2021 14:00:38
User entered 'No (N)'	System	21 Mar 2021 14:00:38

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-21T10:00:30-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '75c3d2aa-e68c-460e-ad87-a0f1c83439df'	System	21 Mar 2021 14:00:38
User entered 'No (N)'	System	21 Mar 2021 14:00:38

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-21T10:00:33-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '75c3d2aa-e68c-460e-ad87-a0f1c83439df' User entered '21 Mar 2021 10:00:33'	System	21 Mar 2021 14:00:38
	System	21 Mar 2021 14:00:38

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-27T11:25:45-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbdd157a-95d1-47e3-8c2e-6a33762fc48d' User entered 'No (N)'	System	27 Mar 2021 15:25:53
	System	27 Mar 2021 15:25:53

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-27T11:25:47-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbdd157a-95d1-47e3-8c2e-6a33762fc48d'	System	27 Mar 2021 15:25:53
User entered 'No (N)'	System	27 Mar 2021 15:25:53

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-27T11:25:50-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbdd157a-95d1-47e3-8c2e-6a33762fc48d' User entered '27 Mar 2021 11:25:50'	System	27 Mar 2021 15:25:53
	System	27 Mar 2021 15:25:53

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-03T07:08:31-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'f1d6d7f1-418c-447f-a3e5-a1c39f292ed0' User entered 'No (N)'	System	03 Apr 2021 11:08:41
	System	03 Apr 2021 11:08:41

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-03T07:08:33-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'f1d6d7f1-418c-447f-a3e5-a1c39f292ed0'	System	03 Apr 2021 11:08:41
User entered 'No (N)'	System	03 Apr 2021 11:08:41

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-03T07:08:37-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'f1d6d7f1-418c-447f-a3e5-a1c39f292ed0' User entered '03 Apr 2021 07:08:37'	System	03 Apr 2021 11:08:41
	System	03 Apr 2021 11:08:41

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-11T09:49:39-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'abbb6d10-5b6b-477d-baef-328bbf741e57'	System	11 Apr 2021 13:49:46
User entered 'No (N)'	System	11 Apr 2021 13:49:46

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-11T09:49:41-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'abbb6d10-5b6b-477d-baef-328bbf741e57'	System	11 Apr 2021 13:49:46
User entered 'No (N)'	System	11 Apr 2021 13:49:46

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-11T09:49:44-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'abbb6d10-5b6b-477d-baef-328bbf741e57'	System	11 Apr 2021 13:49:46
User entered '11 Apr 2021 09:49:44'	System	11 Apr 2021 13:49:46

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-17T16:04:26-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c1580ae7-ba29-4456-99c6-c1d3be6bdc62'	System	17 Apr 2021 20:04:36
User entered 'No (N)'	System	17 Apr 2021 20:04:36

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-17T16:04:27-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c1580ae7-ba29-4456-99c6-c1d3be6bdc62'	System	17 Apr 2021 20:04:36
User entered 'No (N)'	System	17 Apr 2021 20:04:36

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-17T16:04:30-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'c1580ae7-ba29-4456-99c6-c1d3be6bdc62'	System	17 Apr 2021 20:04:36
User entered '17 Apr 2021 16:04:30'	System	17 Apr 2021 20:04:36

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-25T17:00:25-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbbb9dd3-d111-4f67-b672-37a30be0a264'	System	25 Apr 2021 21:00:37
User entered 'No (N)'	System	25 Apr 2021 21:00:37

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-25T17:00:27-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbbb9dd3-d111-4f67-b672-37a30be0a264'	System	25 Apr 2021 21:00:37
User entered 'No (N)'	System	25 Apr 2021 21:00:37

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-04-25T17:00:29-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'bbbb9dd3-d111-4f67-b672-37a30be0a264'	System	25 Apr 2021 21:00:37
User entered '25 Apr 2021 17:00:29'	System	25 Apr 2021 21:00:37

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-05-01T17:08:39-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3fe498e7-7a9e-4a91-a5ea-970881737474'	System	01 May 2021 21:08:47
User entered 'No (N)'	System	01 May 2021 21:08:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Have you been exposed to someone with 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 (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-05-01T17:08:41-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3fe498e7-7a9e-4a91-a5ea-970881737474'	System	01 May 2021 21:08:47
User entered 'No (N)'	System	01 May 2021 21:08:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-05-01T17:08:44-04:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: '3fe498e7-7a9e-4a91-a5ea-970881737474'	System	01 May 2021 21:08:47
User entered '01 May 2021 17:08:44'	System	01 May 2021 21:08:47

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:34:48

US3412304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:38:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:34:48
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:34:48

US3412304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:38:27

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 00:59:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-06T19:23:04-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a58eb8fe-3655-4fc6-bcbe-6daf307aa371'	System	07 Mar 2021 00:23:27
User entered 'No (N)'	System	07 Mar 2021 00:23:27

US3412304

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:38:27

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:59:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F939A88E-3454-496B-859F-A0172F6133BC)', Time: '2021-03-06T19:23:23-05:00', User OID: 'PatientReportedOutcome (US3412304)', ODM File OID: 'a58eb8fe-3655-4fc6-bcbe-6daf307aa371' User entered '06 Mar 2021 19:23:23'	System	07 Mar 2021 00:23:27
	System	07 Mar 2021 00:23:27

US3412304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 19:47:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Nov 2020 18:15:26

US3412304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 19:47:48
User entered '17 Nov 2020'	Mason Urban (b) (4)	17 Nov 2020 18:15:26

US3412304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	02 Dec 2020 19:47:48
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Nov 2020 18:15:26

US3412304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'This was not indicated due to subject being in the convalescent period at the time.' reason for change: Data Entry Error	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	02 Dec 2020 19:47:48
	(b) (4)	
	Mason Urban (b) (4)	17 Nov 2020 18:15:26
	(b) (4)	

US3412304

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Nov 2020 18:15:11

US3412304

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:20:53
User entered 'I'	System	17 Nov 2020 18:15:11

US3412304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Dec 2020 14:39:02

US3412304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '21 Dec 2020'	Mason Urban (b) (4)	21 Dec 2020 14:39:02

US3412304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Dec 2020 14:39:02

US3412304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	21 Dec 2020 14:39:02

US3412304

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Dec 2020 14:39:13

US3412304

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User entered 'I'	System	21 Dec 2020 14:39:13

US3412304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'No (N)'	Mason Urban (b) (4)	18 Feb 2021 16:51:37

US3412304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 16:51:37

US3412304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 16:51:37

US3412304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'PATIENT NOT CALLED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE REGULAR SAFETY CALLS ALONGSIDE OPEN LABEL PHASE'	Mason Urban (b) (4)	18 Feb 2021 16:51:37

US3412304

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 16:50:29

US3412304

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User entered 'I'	System	18 Feb 2021 16:50:29

US3412304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 16:50:39

US3412304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Feb 2021'	Mason Urban (b) (4)	18 Feb 2021 16:50:39

US3412304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	18 Feb 2021 16:50:39

US3412304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 16:50:39

US3412304

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 16:50:43

US3412304

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:53:16
User entered 'I'	System	18 Feb 2021 16:50:43

US3412304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	(b) (4)	18 Mar 2021 18:18:07
User entered 'Yes (Y)' reason for change: Data Entry Error	System	18 Mar 2021 18:18:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 18:18:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Mar 2021 18:17:58
User opened query 'Was this visit performed is No, however Visit Date is provided. Please correct.' (Site from System).	System	18 Mar 2021 18:17:58
User entered 'No (N)' reason for change: Data Entry Error	System	18 Mar 2021 18:17:58
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 18:17:44
User entered empty.	System	18 Mar 2021 18:17:44

US3412304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Mar 2021' reason for change: New Information	(b) (4)	25 Mar 2021 12:57:30
User closed query 'Per CDM: Thank you for confirming the date; However please clarify why the visit performed out of window in query response. ' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 05:15:21
Query 'Per CDM: Thank you for confirming the date; However please clarify why the visit performed out of window in query response. ' answered with 'CONFIRM' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:07:36
User opened query 'Per CDM: Thank you for confirming the date; However please clarify why the visit performed out of window in query response. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 09:43:55
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 09:43:35
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CONFIRMED' (Site from System).	(b) (4), (b) (6)	18 Mar 2021 18:20:28
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Mar 2021 18:19:31
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	18 Mar 2021 18:17:44
User entered '26 Feb 2021'	(b) (4), (b) (6)	18 Mar 2021 18:17:44

US3412304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

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 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	(b) (4)	18 Mar 2021 18:18:07
User opened query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	18 Mar 2021 18:17:58
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Mar 2021 18:17:44

US3412304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'VISIT4'	System	18 Mar 2021 18:17:58
User entered empty.	System	18 Mar 2021 18:17:44

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:11'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '25 Mar 2021 08:11'	System	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'bpm'	System	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'breaths/min'	System	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '110'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'mmHg'	System	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'mmHg'	System	31 Mar 2021 16:00:45

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34

US3412304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34

US3412304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:18:16

US3412304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:18:16

US3412304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25-Mar-2021 is recorded under Visit 4 Day 209 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.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 08:34:18
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25-Mar-2021 is recorded under Visit 4 Day 209 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).		29 Mar 2021 08:34:12
User entered 'Yes (Y)'		18 Mar 2021 18:19:07

US3412304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	25 Mar 2021 12:58:21
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	25 Mar 2021 12:58:21
User entered '25 Mar 2021' reason for change: New Information	(b) (4), (b) (6)	25 Mar 2021 12:58:21
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	25 Mar 2021 12:57:30
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Mar 2021 18:19:31
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	18 Mar 2021 18:19:31
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	18 Mar 2021 18:19:07
User entered '24 Feb 2021'	(b) (4), (b) (6)	18 Mar 2021 18:19:07

US3412304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:31' reason for change: New Information	(b) (4)	25 Mar 2021 12:58:21
User entered '13:03'	(b) (4), (b) (6)	18 Mar 2021 18:19:07

US3412304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered '25 Mar 2021 08:31'	System	25 Mar 2021 12:58:21
User entered '24 Feb 2021 13:03'	System	18 Mar 2021 18:19:07

US3412304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:19:55

US3412304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:22:34
User entered 'I'	System	18 Mar 2021 18:19:55

US3412304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:04:32

US3412304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:04:32

US3412304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:04:32

US3412304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:04:32

US3412304

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:04:35

US3412304

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 18:04:35

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:27

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:23:43
User entered '05 Nov 2020'		05 Nov 2020 16:48:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:27

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:23:43
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:49:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:49:20
User entered '11:00' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:49:20
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:48:58
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:48:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:27

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:51
User entered '05 Nov 2020 11:00'	System	05 Nov 2020 16:49:20
User entered empty.	System	05 Nov 2020 16:48:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:27

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:23:43
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:49:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Nov 2020 16:49:20
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 16:49:20
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:48:58
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:48:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:38:27

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:23:43
User entered 'Yes (Y)'		05 Nov 2020 16:48:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User closed query 'Please reconcile as AE start date = 03Nov2020. Per CCG's symptom log day 1 = day subject first experienced symptoms. Please add 03Nov and 04Nov to Lines 14 and 15. Then you must update symptom day # in lines 1-13 to reflect 05Nov20 starts symptom log Day 3' (Site from CRA).		19 Nov 2020 17:47:28
Query 'Please reconcile as AE start date = 03Nov2020. Per CCG's symptom log day 1 = day subject first experienced symptoms. Please add 03Nov and 04Nov to Lines 14 and 15. Then you must update symptom day # in lines 1-13 to reflect 05Nov20 starts symptom log Day 3' answered with 'UPDATED ALL' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:37
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User opened query 'Please reconcile as AE start date = 03Nov2020. Per CCG's symptom log day 1 = day subject first experienced symptoms. Please add 03Nov and 04Nov to Lines 14 and 15. Then you must update symptom day # in lines 1-13 to reflect 05Nov20 starts symptom log Day 3' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:47:53
User entered 'Day 1 (Day 1)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '05 Nov 2020'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User closed query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' (Site from CRA).		11 Feb 2021 17:50:26
DataPoint Verified.		11 Feb 2021 17:49:54
User closed query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).		18 Jan 2021 11:56:36
Query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' answered with 'UPDATED TO NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:53:26
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:53:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4) (b) (4)	14 Jan 2021 16:53:17
User opened query 'Per CDM : It appears that O2 saturation was not collected. If not collected, please consider recording it as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 15:22:59
Query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' answered with 'was original illness visit, saturation was not on source.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:54:08
User opened query 'Per ETRTR, Please enter data. If not done, please ensure a PD is recorded.' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 20:09:15
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	14 Jan 2021 16:53:17
User entered empty.	System	05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '37.1' C		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		05 Nov 2020 16:51:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 2 (Day 2)'	(b) (4), (b) (6)	06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '06 Nov 2020'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '94'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '97.5' F		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data no required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		06 Nov 2020 18:32:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 3 (Day 3)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		11 Feb 2021 17:53:06
DataPoint Un-verified.	Melissa Fuson (b) (4)	30 Nov 2020 18:37:28
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Melissa Fuson (b) (4)	30 Nov 2020 18:37:28
	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '7 Nov 2020'	Jacob sekinger (b) (4)	10 Nov 2020 19:59:28
	(b) (4)	

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '92'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '98.9' F	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 19:59:28

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 4 (Day 4)'	(b) (4), (b) (6)	13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '08 Nov 2020'		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'I'		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered empty.	System	13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	(b) (4), (b) (6)	13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered empty.		13 Nov 2020 15:07:55

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 5 (Day 5)'	(b) (4), (b) (6)	13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '09 Nov 2020'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '95'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '99.2' F		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:09:32

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '10 Nov 2020'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '92'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '98.9' F		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:11:29

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 7 (Day 7)'	(b) (4), (b) (6)	13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '11 Nov 2020'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '94'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '98.4' F		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:12:43

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 8 (Day 8)'	(b) (4), (b) (6)	13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '12 Nov 2020'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '95'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '97.9' F		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Mild (Mild)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Severe (Severe)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 15:14:06

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 11 (Day 11)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 9 (Day 9)'	(b) (4), (b) (6)	13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '13 Nov 2020'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '0'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '93'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered '100.6' F		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Severe (Severe)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User entered 'None (None)'		13 Nov 2020 18:56:36

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 12 (Day 12)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 10 (Day 10)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '14 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '97'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '98.7' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 16:15:40
User closed query 'None per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 16:15:38
Query 'None per source? Please confirm and update accordingly' answered with 'no nausea noted on day 12 in source' (Site from CRA).	Steven Anderson (b) (4)	20 Nov 2020 16:14:59
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 16:14:46
User opened query 'None per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 17:55:05
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:38
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:56:04

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 05 Nov 2020 symptom log on log line 11. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 19:18:00
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 05 Nov 2020 symptom log on log line 11. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'updated' (Site from DM).		20 Apr 2021 17:07:02
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 05 Nov 2020 symptom log on log line 11. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).		20 Apr 2021 09:23:06
User signature succeeded.		
DataPoint activated with code reason code Data required.	Richard Powell (b) (4) (b) (4) (b) (4), (b) (6)	16 Apr 2021 18:18:34 11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 13 (Day 13)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 11 (Day 11)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '15 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '93'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '98.7' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:43:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 22:07:59
DataPoint Un-verified.		20 Apr 2021 17:05:45
Signature has been broken.		20 Apr 2021 17:05:45
User entered 'None (None)' reason for change: Data Entry Error		20 Apr 2021 17:05:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:58:16

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:10:03
User entered 'Day 12 (Day 12)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '16 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '93'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '97.5' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:00:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:10:03
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
Query 'please enter 18 Nov 2020 log line' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:36:51
User opened query 'please enter 18 Nov 2020 log line' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:31:10
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '17 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '93'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		19 Nov 2020 17:54:25
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 21:58:25
User entered '98.4' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:58:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Nov 2020 21:50:14
User entered '98.4' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:50:14

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:06:10
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 1 (Day 1)'	Melissa Fuson (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '03 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered empty.	System	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 16:59:22

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:06:10
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:02:01
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '04 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'I'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered empty.	System	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered empty.	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:00:10

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 16 (Day 16)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:10:03
User entered 'Day 14 (Day 14)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '18 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '96'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered '97.9' F	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:54:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:09:02

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 17 (Day 17)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:27
User entered '19 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:25
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:23
User entered '93'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:31
User entered '97.1' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:36
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:01
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:00
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:58
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:12:57
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:06
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:12
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 22:13:11
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:36:41

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 18 (Day 18)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:52
User entered '20 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:04
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:03
User entered '98'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:01
User entered '97.6' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:24
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:44
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:37
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:58
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:39:08

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 19 (Day 19)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:41:07
User entered 'Day 20 (Day 20)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:13:33
User entered '21 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:13:36
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:13:45
User entered '97'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:13:47
User entered '97.3' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:13:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:02
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:11
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:33
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:34
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:36
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:38
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 13:40:45

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 20 (Day 20)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		24 Nov 2020 17:10:15
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 21:03:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 21:03:50
User entered '22 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:03:50
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 21:01:40
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:17
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:25
User entered '95' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	23 Nov 2020 21:03:50
User entered empty.	System	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:27
User entered '97.9' F reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:32
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:33
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:35
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:37
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:10:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User closed query 'Please provide response. None per source' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:27:47
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:27:45
Query 'Please provide response. None per source' answered with 'updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:28:10
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	24 Nov 2020 20:28:01
User opened query 'Please provide response. None per source' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 17:11:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:19
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:20
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:23
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:25
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:26
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:28
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:29
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:31
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:12:32
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:03:50
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 21 (Day 21)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
DataPoint Verified.		24 Nov 2020 17:07:44
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 21:06:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Nov 2020 21:06:08
User entered '23 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:06:08
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Nov 2020 21:01:40
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:40
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:41
User entered '96' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	23 Nov 2020 21:06:08
User entered empty.	System	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 21:06:28
User entered '97.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:06:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 21:06:08
User entered '97.1' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:45
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:46
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:48
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:50
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:58
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:00
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

Body Aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:01
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:03
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:05
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:06
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:08
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:14
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:15
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:17
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:19
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:09:21
User entered 'None (None)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 21:06:08
User entered empty.	Melissa Fuson (b) (4)	23 Nov 2020 21:01:40

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User closed query '24 Nov 2020 should be Day 22 - need to enter data for 24 Nov 2020 - 25 Nov 2020 and on will need to shift days' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 17:57:39
Query '24 Nov 2020 should be Day 22 - need to enter data for 24 Nov 2020 - 25 Nov 2020 and on will need to shift days' answered with 'dates have been updated.' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 18:46:32
User opened query '24 Nov 2020 should be Day 22 - need to enter data for 24 Nov 2020 - 25 Nov 2020 and on will need to shift days' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 18:35:47
User entered 'Day 22 (Day 22)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 17:57:47
DataPoint Un-verified.	Jacob sekinger (b) (4)	02 Dec 2020 18:46:14
User entered '24 Nov 2020' reason for change: Data Entry Error	(b) (4)	02 Dec 2020 18:46:14
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:36:44
User entered '25 Nov 2020'	Melissa Fuson (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:36:52
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:36:50
User entered '97'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:36:55
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:12
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:15
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:51
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:53
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:37:58
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:38:00
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:38:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:38:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:38:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (22)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:38:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:43:24

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 23 (Day 23)' reason for change:	Melissa Fuson (b) (4)	30 Nov 2020 18:45:50
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:45:25
	(b) (4)	

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'Day 22 was 24 Nov 2020. Day 23 should be 25 Nov 2020. Please add 25 Nov 2020 and shift dates/symptom days and update with missing information as appropriate' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:23:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	11 Feb 2021 21:23:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:47
Query 'Day 22 was 24 Nov 2020. Day 23 should be 25 Nov 2020. Please add 25 Nov 2020 and shift dates/symptom days and update with missing information as appropriate' answered with 'this has been updated to indicate day 23 of symptoms and telemedicine visit day 21 signs and symptoms' (Site from CRA). User entered '25 Nov 2020' reason for change: Data Entry Error DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4) (b) (4), (b) (6)	11 Feb 2021 20:11:47
User opened query 'Day 22 was 24 Nov 2020. Day 23 should be 25 Nov 2020. Please add 25 Nov 2020 and shift dates/symptom days and update with missing information as appropriate' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 18:01:20
User entered '26 Nov 2020'	(b) (4), (b) (6) Melissa Fuson (b) (4) (b) (4)	01 Dec 2020 18:39:37 30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:39:41
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:39:43
User entered '97'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:16:29
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:11:05
User entered '98.2' F reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:11:05
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:39:45
User entered '97.5' F	Melissa Fuson (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:39:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:16:33
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:11:05
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	11 Feb 2021 20:11:05
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:09
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:37
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:46
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (23)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:40:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:45:25

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 24 (Day 24)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:26
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
User entered '26 Nov 2020' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	11 Feb 2021 20:12:31
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:29
User entered '27 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:32
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:08
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
User entered '97' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:37
User entered '96'	Melissa Fuson (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:10
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
User entered '97.5' F reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:40
User entered '96.8' F	Melissa Fuson (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:57
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:41:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:04
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:06
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:08
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:18
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:31
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	11 Feb 2021 20:12:31
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (24)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:42:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:47:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 25 (Day 25)' reason for change:	Melissa Fuson (b) (4)	30 Nov 2020 18:50:02
Data Entry Error	(b) (4)	
User entered empty.	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:41
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:59
User entered '27 Nov 2020' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	11 Feb 2021 20:12:59
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:16
User entered '28 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:18
User entered '0'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:45
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:59
User entered '96' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:12:59
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:19
User entered '98'	Melissa Fuson (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:17:46
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Feb 2021 20:12:59
User entered '96.8' F reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:12:59
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:21
User entered '96.5' F	Melissa Fuson (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:36
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:42
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:51
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:54
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:43:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:44:02
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:44:06
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:44:08
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (25)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:44:11
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:49:42

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
User entered 'Day 26 (Day 26)'	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:10
User entered '28 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered '29 Nov 2020'	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:15
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered '1'	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:19
User entered '98' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
DataPoint activated with code reason code Data required.		11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.		11 Feb 2021 21:20:09
User entered '%'	System	11 Feb 2021 20:14:11
User entered empty.	System	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

Temperature

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:20
User entered '96.5' F reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Symptom Log (26)

Generated On: 11 Aug 2021 22:38:27

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:51:57
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint activated with code reason code Data required.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:20:47
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	11 Feb 2021 21:20:09
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:18:34
User entered 'None (None)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Feb 2021 20:14:11
User entered empty.	Melissa Fuson (b) (4)	30 Nov 2020 18:50:48

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered '05 Nov 2020'		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[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 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered 'Yes (Y)'		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

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 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
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).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 13:54:16
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:06:03
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 'VERIFIED THROUGH SOURCE OF PPD RECORD.' (Site from System).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:33:16
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 20:32:51
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 20:32:51
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	17 Nov 2020 20:32:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:32:51
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 16:52:26
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered '05 Nov 2020'		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered empty.		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[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 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered 'No (N)'		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered empty.		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:06:03
User entered empty.		05 Nov 2020 16:52:26

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:38:27

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:02
User entered 'I'	System	17 Nov 2020 20:32:51

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[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 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

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 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User closed query 'Please reconcile as symptom log indicates subject had 93% or lower beginning on 07Nov2020 and ongoing' (Site from CRA).		20 Nov 2020 04:35:38
Query 'Please reconcile as symptom log indicates subject had 93% or lower beginning on 07Nov2020 and ongoing' answered with 'UPDATED PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:13:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:13:40
User opened query 'Please reconcile as symptom log indicates subject had 93% or lower beginning on 07Nov2020 and ongoing' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 03:33:38
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User closed query 'please enter first date O2 was </=93% (07 Nov 2020 was 92% per source)' (Site from CRA).		21 Nov 2020 17:59:49
Query 'please enter first date O2 was </=93% (07 Nov 2020 was 92% per source)' answered with 'Subjects o2 changed every day however this was the lowest documented o2 stat date' (Site from CRA).	Steven Anderson (b) (4)	20 Nov 2020 15:23:50
User entered '07 Nov 2020' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 14:57:01
User opened query 'please enter first date O2 was </=93% (07 Nov 2020 was 92% per source)' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:26:27
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 05:37:51
User closed query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 17 (19NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 19:15:53
Query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 17 (19NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' answered with 'information has been updated' (Site from DM). DataPoint Un-verified.		22 Apr 2021 17:54:53
Signature has been broken.		22 Apr 2021 13:03:18
User entered '19 Nov 2020' reason for change: Data Entry Error User opened query 'Per CDM : Please note as per the Symptom log the O2 saturation is 93% on Day 17 (19NOV2020), Kindly check the end date in severity form as it does not reconcile with the symptom log and make appropriate corrections or else clarify. Thanks' (Site from DM). User signature succeeded.		22 Apr 2021 13:02:58
DataPoint Verified.		22 Apr 2021 13:02:58
User closed query 'Re-query: Last date subject experienced an O2 <= 93% was 17Nov2020. Please correct end date' (Site from CRA). User entered '17 Nov 2020' reason for change: Data Entry Error	Richard Powell (b) (4) (b) (4) (b) (4), (b) (6)	21 Apr 2021 12:25:20
	Richard Powell (b) (4)	16 Apr 2021 18:18:34
	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
		23 Nov 2020 16:23:41
	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 16:16:58

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Query 'Re-query: Last date subject experienced an O2 $\leq 93\%$ was 17Nov2020. Please correct end date' answered with 'updated o2 saturation for 21-nov-2020 of 97%' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 13:44:24
User entered '21 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User opened query 'Re-query: Last date subject experienced an O2 $\leq 93\%$ was 17Nov2020. Please correct end date' (Site from CRA).	Melissa Fuson (b) (4)	23 Nov 2020 13:43:36
User closed query 'please enter last date O2 was $\leq 93\%$ (per source a of today would be 17 Nov 2020 when it was 93%)' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:59:37
Query 'please enter last date O2 was $\leq 93\%$ (per source a of today would be 17 Nov 2020 when it was 93%)' answered with 'Subjects o2 changed every day however this was the lowest documented o2 stat date' (Site from CRA).	(b) (4)	
User entered '07 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Nov 2020 15:23:54
User opened query 'please enter last date O2 was $\leq 93\%$ (per source a of today would be 17 Nov 2020 when it was 93%)' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 14:57:01
User entered empty.	(b) (4)	19 Nov 2020 18:26:29
	Melissa Fuson (b) (4)	17 Nov 2020 21:02:46
	(b) (4)	

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered '92' reason for change: Data Entry Error	Steven Anderson (b) (4)	23 Nov 2020 16:16:16
User entered '97' reason for change: Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 13:43:36
User closed query 'please enter lowest O2 value between start /stop dates above (92% per source - please confirm and update accordingly)' (Site from CRA).	(b) (4), (b) (6)	21 Nov 2020 17:59:42
Query 'please enter lowest O2 value between start /stop dates above (92% per source - please confirm and update accordingly)' answered with 'Subjects o2 changed every day however this was the lowest documented o2 stat date' (Site from CRA).	Steven Anderson (b) (4)	20 Nov 2020 15:23:59
User entered '92' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Nov 2020 14:57:01
User opened query 'please enter lowest O2 value between start /stop dates above (92% per source - please confirm and update accordingly)' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:28:20
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:03:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Nov 2020 21:03:01
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:03:01
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Nov 2020 21:02:46
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[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 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:38:27

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:23:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:02:46

US3412304

Folder: Covid-19 Assessment 05 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:38:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:52:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:07:17
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 20:41:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 16:48:26

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:16
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07,09,11,13,18NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 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) (4), (b) (6)	14 Dec 2020 07:35:00
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07,09,11,13,18NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 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 PPD SOURCE GENERATED ON 25-NOV-2020 WITH ACCESSION NUMBER: 1F60AHQ (b) (6) SAMPLES WERE RECEIVED BY PPD.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	10 Dec 2020 13:25:04
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 07,09,11,13,18NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 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)	04 Dec 2020 07:11:27
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:19
User entered '07 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:31
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Apr 2021 12:35:00
User closed query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' (Site from DM).		26 Mar 2021 05:54:56
Query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' answered with 'updated' (Site from DM).		23 Mar 2021 18:45:55
DataPoint Un-verified.		23 Mar 2021 18:45:43
User entered '24 Nov 2020' reason for change: Data Entry Error		23 Mar 2021 18:45:43
User opened query 'Per GCL Lab Recon: Saliva: The Collection dates for Illness visit day 3-21 = 24NOV2020 in PPD Central Lab, if EDC is correct kindly confirm if data can be updated in PPD via DCF. Thanks ' (Site from DM).		23 Mar 2021 07:01:25
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:29:34
User entered '09 Nov 2020'	Steven Anderson (b) (4)	20 Nov 2020 16:14:04
	(b) (4)	

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:46
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:44
User entered '11 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:55
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:29:56
User entered '13 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:30:13
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 18:30:15
User entered '18 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Dec 2020 18:30:27
User closed query 'Data is required. Please complete.' (Site from System).	System	30 Nov 2020 21:02:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Nov 2020 21:02:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Nov 2020 21:02:32
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:14:04
User entered empty.	Steven Anderson (b) (4)	20 Nov 2020 16:14:04
	(b) (4)	

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 14 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 07:30:53
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 14 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. ' answered with 'edc is correct will update with ppd' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 14:21:48
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 25NOV2020 is recorded under Illness Visit Day 21 in EDC, however the same is reported under COVID PCR Saliva Day 14 in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, Thank you. '(Site from DM).	(b) (4), (b) (6)	02 Apr 2021 06:51:44
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 18:30:29
User entered '25 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 21:02:32
User entered empty.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:27

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:27

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:09:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:01:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 18:51:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 18:51:02
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	02 Dec 2020 18:51:02
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:14:04
User entered empty.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:09:52
User entered '3 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:01:59
User entered empty.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:14:04

US3412304

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'please complete saliva collection CRF' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 18:00:14
Query 'please complete saliva collection CRF' answered with 'saliva collection log has been filled out' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:15:41
User opened query 'please complete saliva collection CRF' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:52:24
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:45:28
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:45:28
User entered '5 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:45:28
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'SICKD1'	System	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '5 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '11:05'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered '5 Nov 2020 11:05'	System	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '174' cm	Melissa Fuson (b) (4)	17 Nov 2020 20:43:50
DataPoint set to visible.	(b) (4) System	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '109' kg	Melissa Fuson (b) (4)	17 Nov 2020 20:43:50
DataPoint set to visible.	(b) (4) System	17 Nov 2020 20:42:45

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '37.1' C	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '96'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'bpm'	System	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '16'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'breaths/min'	System	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '130'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'mmHg'	System	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:01
User entered '79'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User entered 'mmHg'	System	17 Nov 2020 20:43:50

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42

US3412304

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42

US3412304

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:12
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:44:11

US3412304

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:12
User entered '5 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:44:11

US3412304

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:38:27

[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 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:18
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:46:51

US3412304

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:46:18
User entered '5 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 20:46:51

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:09
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:09
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered 'SICKD28'	System	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '09:10'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered '3 Dec 2020 09:10'	System	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '177.5' cm	Melissa Fuson (b) (4)	03 Dec 2020 15:00:31
DataPoint set to visible.	(b) (4) System	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '109.9' kg	Melissa Fuson (b) (4)	03 Dec 2020 15:00:31
DataPoint set to visible.	(b) (4) System	03 Dec 2020 14:58:34

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '36.8' C	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '78'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered 'bpm'	System	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '18'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered 'breaths/min'	System	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '128'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered 'mmHg'	System	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:34
User entered '76'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User entered 'mmHg'	System	03 Dec 2020 15:00:31

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:50
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:48

US3412304

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:07:50
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:00:48

US3412304

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:38:27

[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 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:08:08
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:01:03

US3412304

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:38:27

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:08:08
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:01:03

US3412304

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:25:45

US3412304

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:25:45

US3412304

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	22 Jan 2021 15:25:45

US3412304

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

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'UNBLND_DECIDE'	System	22 Jan 2021 15:25:45

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User closed query 'please complete' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 16:39:37
Query 'please complete' answered with 'UPDATED' (Site from CRA).	(b) (4)	18 Mar 2021 18:13:44
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
User opened query 'please complete' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 12:42:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:45:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '1'	System	22 Jan 2021 15:25:59

US3412304

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

Form: Unblinding

Generated On: 11 Aug 2021 22:38:27

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	22 Jan 2021 15:25:59

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '174.7' cm	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '107.8' kg	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '35.32100'	System	22 Jan 2021 15:27:47
DataPoint set to visible.	System	22 Jan 2021 15:25:59

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '174.7' cm	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '107.8' kg	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '35.32100'	System	22 Jan 2021 15:27:47
DataPoint set to visible.	System	22 Jan 2021 15:25:59

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '9:15'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '18 Jan 2021 9:15'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '36.7' C	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '80'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'bpm'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'breaths/min'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '118'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '70'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '174.7' cm	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '107.8' kg	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:38:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '35.32100'	System	22 Jan 2021 15:27:47
DataPoint set to visible.	System	22 Jan 2021 15:25:59

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '9:59'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '18 Jan 2021 9:59'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '98.1' F	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'bpm'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'breaths/min'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '122'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '74'	Mason Urban (b) (4)	22 Jan 2021 15:27:47

US3412304

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	22 Jan 2021 15:27:47

US3412304

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:27:53

US3412304

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:27:53

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mRNA-1273'	System	22 Jan 2021 15:28:07
DataPoint set to visible.	System	22 Jan 2021 15:25:59

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '9:30'	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '18 Jan 2021 9:30'	System	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4)	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'ONCE'	System	22 Jan 2021 15:28:07

US3412304

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

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'INTRAMUSCULAR'	System	22 Jan 2021 15:28:07

US3412304

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:26:10

US3412304

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:26:10

US3412304

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '8:25'	Mason Urban (b) (4)	22 Jan 2021 15:26:10

US3412304

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '18 Jan 2021 8:25'	System	22 Jan 2021 15:26:10

US3412304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:26:23

US3412304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '18 Jan 2021'	Mason Urban (b) (4)	22 Jan 2021 15:26:23

US3412304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '8:37'	Mason Urban (b) (4)	22 Jan 2021 15:26:23

US3412304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:38:27

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '18 Jan 2021 8:37'	System	22 Jan 2021 15:26:23

US3412304

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

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 15:26:28

US3412304

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

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	22 Jan 2021 15:26:28

US3412304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 15:44:49

US3412304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered '25 Jan 2021'	Mason Urban (b) (4)	25 Jan 2021 15:44:49

US3412304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Jan 2021 15:44:49

US3412304

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered empty.	Mason Urban (b) (4)	25 Jan 2021 15:44:49

US3412304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 15:44:53

US3412304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	25 Jan 2021 15:44:53

US3412304

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	25 Jan 2021 15:44:53
DataPoint set to visible.	System	25 Jan 2021 15:44:53

US3412304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:37:20

US3412304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:37:20

US3412304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	25 Feb 2021 17:37:20

US3412304

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'OLD29'	System	25 Feb 2021 17:37:20

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06
	(b) (4)	

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '07:21'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '25 Feb 2021 07:21'	System	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '36.9' C	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'bpm'	System	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '14'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'breaths/min'	System	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '110'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Feb 2021 17:38:06

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:52'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '25 Feb 2021 08:52'	System	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '97.8' F	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '70'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'bpm'	System	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '16'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'breaths/min'	System	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '125'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '70'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Feb 2021 17:38:34

US3412304

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:44

US3412304

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:38:44

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mRNA-1273'	System	25 Feb 2021 17:39:01
DataPoint set to visible.	System	25 Jan 2021 15:44:53

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:21'	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '25 Feb 2021 08:21'	System	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Left Arm (LEFT ARM)'	Andrea Newlands (b) (4)	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'ONCE'	System	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:38:27

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 17:39:01

US3412304

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:36:32

US3412304

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	25 Feb 2021 17:36:32

US3412304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Mar 2021 15:16:53

US3412304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered '5 Mar 2021'	Mason Urban (b) (4)	05 Mar 2021 15:16:53

US3412304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	05 Mar 2021 15:16:53

US3412304

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:38:27

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered empty.	Mason Urban (b) (4)	05 Mar 2021 15:16:53

US3412304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:41:24
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Mar 2021 15:17:11

US3412304

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:38:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'I'	System	05 Mar 2021 15:17:11

US3412304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:59:06

US3412304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:59:06

US3412304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[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 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 12:59:06

US3412304

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:38:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'OLD57'	System	25 Mar 2021 12:59:06

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:11'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '25 Mar 2021 08:11'	System	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'bpm'	System	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'breaths/min'	System	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '110'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '72'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered 'mmHg'	System	25 Mar 2021 13:00:08

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21

US3412304

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:38:27

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21

US3412304

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:30

US3412304

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:38:27

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:00:30

US3412304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:01:04

US3412304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:01:04

US3412304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
User entered '08:31'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:01:04

US3412304

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:38:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:14:21
User entered '25 Mar 2021 08:31'	System	25 Mar 2021 13:01:04

US3412304

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:38:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:30:14
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	10 Nov 2020 20:03:27
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:11:08

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	19 Nov 2020 17:36:07
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:52:00
User entered	System	11 Nov 2020 21:51:19
'USA-US061-2020-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	11 Nov 2020 21:51:19

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Dec 2020 03:29:01
User closed query 'Per CCG term should be Symptomatic COVID-19 - please update' (Site from CRA).		19 Dec 2020 03:28:58
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 15:12:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Dec 2020 15:12:22
Query 'Per CCG term should be Symptomatic COVID-19 - please update' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:11:06
Data point term sent to Coder	System	11 Dec 2020 15:11:04
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
User opened query 'Per CCG term should be Symptomatic COVID-19 - please update' (Site from CRA).	(b) (4), (b) (6)	06 Dec 2020 21:58:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 18:59:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Nov 2020 18:59:03
Data point term sent to Coder	System	30 Nov 2020 18:58:06
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:57:43
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:57:43
User entered 'COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:57:43
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 22:42:20

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. DataPoint Verified.	Coder Import (b) (4)	24 Nov 2020 22:42:20
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 22:42:17
Data point term sent to Coder	System	24 Nov 2020 22:41:09
DataPoint Un-verified.	Steven Anderson (b) (4)	24 Nov 2020 22:40:29
	(b) (4)	
Coding entries removed.	Steven Anderson (b) (4)	24 Nov 2020 22:40:29
	(b) (4)	
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 22:40:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Nov 2020 04:35:12
Query 'Per CRF Guidelines, please update term to Symptomatic COVID-19' canceled (Site from CRA). DataPoint Un-verified.		20 Nov 2020 04:35:09
		19 Nov 2020 18:56:22
User opened query 'Per CRF Guidelines, please update term to Symptomatic COVID-19' (Site from CRA).		19 Nov 2020 18:53:45
DataPoint Verified.		19 Nov 2020 17:36:07
		18 Nov 2020 22:18:38
User closed query 'PV Query: As the subject had a positive COVID-19 test and signs and symptoms, please consider updating the event from "possible COVID-19" to "COVID-19".' (Site from Safety).		
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)	17 Nov 2020 20:39:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 20:39:49
Data point term sent to Coder	System	17 Nov 2020 20:23:01
Query 'PV Query: As the subject had a positive COVID-19 test and signs and symptoms, please consider updating the event from "possible COVID-19" to "COVID-19".' answered with 'UPDATED PER PV QUERY' (Site from Safety).	Melissa Fuson (b) (4)	17 Nov 2020 20:22:46
Coding entries removed.	(b) (4)	
	Melissa Fuson (b) (4)	17 Nov 2020 20:22:22
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 20:22:22
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: As the subject had a positive COVID-19 test and signs and symptoms, please consider updating the event from "possible COVID-19" to "COVID-19".' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:44:18
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:24:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:24:40
Data point term sent to Coder	System	10 Nov 2020 20:09:13
User entered 'possible COVID-19'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
User closed query 'Please reconcile as per protocol an illness visit is a medically attended AE' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
Query 'Please reconcile as per protocol an illness visit is a medically attended AE' answered with 'UPDATED TO YES' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:15:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:14:53
User opened query 'Please reconcile as per protocol an illness visit is a medically attended AE' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:46:11
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '3 Nov 2020'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:42
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Dec 2020 15:10:53
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Dec 2020 15:10:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:44
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:11:22
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 'this has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:11:13
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
User entered '28 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
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).		17 Nov 2020 17:42:59
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered 'Not Related (NOT RELATED)'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User closed query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		18 Nov 2020 22:18:46
Query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.'	Melissa Fuson (b) (4)	17 Nov 2020 20:24:30
answered with 'UPDATED' (Site from Safety).	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Melissa Fuson (b) (4)	17 Nov 2020 20:22:22
reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 21 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:43:44
User entered 'None (NONE)'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:03:23
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	30 Nov 2020 19:00:41
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 19:00:41
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 19:00:41
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	30 Nov 2020 18:57:43
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '1'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:03:20
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:57:43
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	30 Nov 2020 18:57:43
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered '0'	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:35:52
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	14 Dec 2020 15:11:28
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 'this has been updated' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:11:21
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Steven Anderson (b) (4) (b) (4)	11 Dec 2020 15:10:53
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
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).		17 Nov 2020 17:43:58
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[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 15:40:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:36:07
User entered empty.	Jacob sekinger (b) (4) (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:40:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Dec 2020 03:29:19
User closed query 'Please update narrative to include chronological summary of event, including dates (when is last evening?) conmeds taken, any other pertinent info through conclusion of event. Please correct spelling (since, SOB)' (Site from CRA).		19 Dec 2020 03:29:16
User closed query 'PV Query: COVID-19 Assessments tab for 24 Nov 2020 is missing, please update so.' (Site from Safety).		14 Dec 2020 15:11:38
Query 'PV Query: COVID-19 Assessments tab for 24 Nov 2020 is missing, please update so.' answered with 'UPDATED WITH INFORMATION FROM SOURCE' (Site from Safety).	Melissa Fuson (b) (4)	11 Dec 2020 15:26:00
Query 'Please update narrative to include chronological summary of event, including dates (when is last evening?) conmeds taken, any other pertinent info through conclusion of event. Please correct spelling (since, SOB)' answered with 'all pertinent summary information has been added. All other detailed information should be found in the illness or covid symptom log. ' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	Steven Anderson (b) (4)	11 Dec 2020 15:20:30
	(b) (4)	
	Steven Anderson (b) (4)	11 Dec 2020 15:19:46
	(b) (4)	
User entered 'SUBJECT REPORTS ON 03-NOV-2020 HE STARTED FEELING FATIGUED AND FEVERISH TEMP WAS 99.9F. REPORTS BODY ACHES SINCE THEN. TEMP WAS 100.1 LAST EVENING (04-Nov-20), NO OTHER SYMPTOMS. DENIED N/V, SDB, COUGH, NOT AWARE OF BEING AROUND ANY ONE WITH POSTIVE COVID. Subject presented for sick visit on 05-nov-2020 and had signs and symptoms until 28-Nov-2020. Subject presented for Day 28 convalescent period on 03-Dec-2020. subject only took tussin DM and pseudophed for symptoms of COVID.' reason for change: Data Entry Error	Steven Anderson (b) (4)	11 Dec 2020 15:19:46
	(b) (4)	

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: COVID-19 Assessments tab for 24 Nov 2020 is missing, please update so.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 19:02:42
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		02 Dec 2020 03:42:07
User opened query 'Please update narrative to include chronological summary of event, including dates (when is last evening?) conmeds taken, any other pertinent info through conclusion of event. Please correct spelling (since, SOB)' (Site from CRA).		01 Dec 2020 19:01:16
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'NO MEDICAL INTERVENTION BUT CON MEDS WERE TAKEN' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:56:56
User closed query 'PV Query: The start date of the event was reported as 03 Nov 2020. Please provide signs and symptoms for the event onset date of 03 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:12
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:36:07
Query 'PV Query: The start date of the event was reported as 03 Nov 2020. Please provide signs and symptoms for the event onset date of 03 Nov 2020.' answered with 'UPDATED NARRATIVE FOR SIGNS AND SYMPTOMS REPORTED IN ADVERSE EVENTS COMMENTS ON SOURCE DATED 05-NOV-2020' (Site from Safety).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 17:21:45

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS ON 03-NOV-2020 HE STARTED FEELING FATIGUED AND FEVERISH TEMP WAS 99.9F. REPORTS BODY ACHES SINCEW THEN. TEMP WAS 100.1 LAST EVENING, NO OTHER SYMPTONS. DENIED N/V, SDB, COUGH, NOT AWARE OF BEING AROUND ANY ONE WITH POSTIVE COVID.' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 17:20:27
User opened query 'PV Query: The start date of the event was reported as 03 Nov 2020. Please provide signs and symptoms for the event onset date of 03 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 17:43:29
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		17 Nov 2020 17:43:15
User entered empty.	Jacob sekinger (b) (4)	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Nov 2020 20:08:50

US3412304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:38:27

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 17:14:53
User entered '0'	System	10 Nov 2020 20:08:50

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:38:27

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:30:14
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:44:27
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	02 Sep 2020 20:11:29

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Oct 2020 22:42:53
User closed query 'Should this be Altace?' (Site from CRA).		25 Oct 2020 22:42:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL, PRODUCTSYNONYM: ALTACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:17:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:17:47
Query 'Should this be Altace?' answered with 'CORRECTED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:17:22
Data point term sent to Coder	System	28 Sep 2020 15:17:08
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: RAMIPRIL, PRODUCTSYNONYM: ALTACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:16:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 15:16:43
User closed query 'DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	System	28 Sep 2020 15:16:19
Query 'DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF.' answered with 'UDPATED' (Site from System).	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:16:19
Data point term sent to Coder	System	28 Sep 2020 15:16:05
User entered 'ALTACE' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:15:57
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:15:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

2665 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ALTAC' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:15:25
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User opened query 'Should this be Altace?' (Site from CRA).	(b) (4), (b) (6)	26 Sep 2020 12:37:35
User opened query 'DM-Coding: Please check spelling and add the active ingredient name(s) in brackets next to the drug name in the eCRF.' (Site from System).	Coder Import (b) (4)	07 Sep 2020 13:23:47
Data point term sent to Coder	(b) (4)	
User entered 'attace'	System	02 Sep 2020 20:13:18
	Jacob sekinger (b) (4)	02 Sep 2020 20:12:30
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'hypertension'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '10'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'twice daily (BID)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2012'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:12:30

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 20:14:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 20:14:52
	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 20:13:21
User entered 'aspirin'	Jacob sekinger (b) (4)	02 Sep 2020 20:13:20
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'hypertension'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '81'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'twice daily (BID)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2012'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:13:20
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:13:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Oct 2020 22:43:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:19:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:19:47
Data point term sent to Coder	System	28 Sep 2020 15:28:41
Data point term sent to Coder	System	28 Sep 2020 15:20:14
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:19:26
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:19:26
User entered 'GLUCOSOMINE' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:19:26
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:08:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Sep 2020 06:08:44
Data point term sent to Coder	System	02 Sep 2020 20:14:27
User entered 'glucosamine'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

PRODUCTION RELEASE (v12.003
EAB) (1725)

2702 of 2984

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Oct 2020 22:43:20
User closed query 'glucosamine not indicated for hypoglycemia - should this be for joint health? Please review and update as appropriate' (Site from CRA).		25 Oct 2020 22:43:16
Query 'glucosamine not indicated for hypoglycemia - should this be for joint health? Please review and update as appropriate' answered with 'REVIEWED AND UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:29:00
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:28:40
User entered 'OSTEOARTHRITIS - LEFT FOOT AND LOWER BACK' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:28:40
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User opened query 'glucosamine not indicated for hypoglycemia - should this be for joint health? Please review and update as appropriate' (Site from CRA).		26 Sep 2020 12:45:30
Query 'glucosamine not indicated for hypoglycemia - should this be for osteoarthritis? Please review and update as appropriate' canceled (Site from CRA).		26 Sep 2020 12:44:59
User opened query 'glucosamine not indicated for hypoglycemia - should this be for osteoarthritis? Please review and update as appropriate' (Site from CRA).		26 Sep 2020 12:41:30
User entered 'hypoglycemia'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 06:02:21
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'this has been updated to the correct dosage per the subject' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:30:49
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:30:11
User entered '500' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:30:11
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:16:38
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		16 Nov 2020 10:20:35
Query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'PER SUBJECT SOURCE 1 CAPSULE IS WHAT THEY TAKE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 19:27:08
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of capsule count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 21:14:27

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '1'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
DataPoint Un-verified.	Steven Anderson (b) (4)	26 Jan 2021 15:30:11
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Jan 2021 15:30:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'capsule (CAPSULE)'	Jacob sekinger (b) (4)	02 Sep 2020 20:14:20
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'Per CDM RQ: Response noted. However, MH start date for OA is recorded as 2012. However, start date of medication for OA is recorded as 2010. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 13:19:53
Query 'Per CDM RQ: Response noted. However, MH start date for OA is recorded as 2012. However, start date of medication for OA is recorded as 2010. Please review and reconcile.' answered with 'this has been updated on con med list to show correct date' (Site from DM).	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 16:13:12
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 16:13:00
User entered 'UN UNK 2012' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 16:13:00
User opened query 'Per CDM RQ: Response noted. However, MH start date for OA is recorded as 2012. However, start date of medication for OA is recorded as 2010. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:29:34
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).		23 Nov 2020 15:29:34
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'THIS WAS CHANGED FROM HYPERLIPIDEMIA TO OA' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 19:28:51
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 21:15:51
DataPoint Verified.		26 Sep 2020 12:46:16

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4)	02 Sep 2020 20:14:20
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:14:20

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: GLIBENCLAMIDE;METFORMIN, PRODUCTSYNONYM: GLUCOVANCE [GLIBENCLAMIDE;METFORMIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Sep 2020 23:52:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 23:52:47
Data point term sent to Coder	System	28 Sep 2020 15:30:45
Coding entries removed.	Melissa Fuson (b) (4)	28 Sep 2020 15:29:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: COMBINATIONS OF ORAL BLOOD GLUCOSE LOWERING DRUGS, PRODUCT: GLIBENCLAMIDE;METFORMIN, PRODUCTSYNONYM: GLUCOVANCE [GLIBENCLAMIDE;METFORMIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:05:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 06:05:40
Data point term sent to Coder	System	02 Sep 2020 20:15:28
User entered 'glucovance'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	25 Oct 2020 22:43:37
User closed query 'should this be hyperglycemia? Please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	25 Oct 2020 22:43:35
Query 'should this be hyperglycemia? Please review and update as appropriate' answered with 'REVIEWED AND UPDATED' (Site from CRA).	Melissa Fuson (b) (4)	28 Sep 2020 15:29:55
DataPoint Un-verified.	(b) (4)	28 Sep 2020 15:29:44
User entered 'HYPERGLYCEMIA' reason for change: Data Entry Error	Melissa Fuson (b) (4)	28 Sep 2020 15:29:44
DataPoint Verified.	(b) (4)	26 Sep 2020 12:46:16
User opened query 'should this be hyperglycemia? Please review and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	26 Sep 2020 12:46:04
User entered 'hypoglycemia'	Jacob sekinger (b) (4)	02 Sep 2020 20:15:13
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g 40/1680). ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 10:20:43
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g 40/1680). ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 19:10:30
DataPoint Un-verified.	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 19:10:22
User entered '500/5' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	13 Nov 2020 19:10:22
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g 40/1680). ' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 21:13:13
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '500'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'twice daily (BID)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2012'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:15:13

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
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, PRODUCTSYNONYM: MOBIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:17:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:17:48
Data point term sent to Coder User entered 'mobic'	System Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:30 02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'osteoarthritis'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '15'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2015'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:16:03

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
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.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:17:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:17:49
Data point term sent to Coder	System	02 Sep 2020 20:17:31
User entered 'multivitamin'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'general health'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'I'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'capsule (CAPSULE)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2014'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:16:43

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:19:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:19:47
Data point term sent to Coder	System	02 Sep 2020 20:18:34
User entered 'omeprazole'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'GERD'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '20'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2014'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:17:38

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Oct 2020 20:19:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:19:22
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4)	19 Oct 2020 20:17:51 19 Oct 2020 20:17:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:19:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 20:19:47
Data point term sent to Coder User entered 'Crestor'	System Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:35 02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Oct 2020 22:45:57
User closed query 'Med Hx term is hyperlipidemia. Please review and update either Med Hx or this indication to match' (Site from CRA).		25 Oct 2020 22:45:55
Query 'Med Hx term is hyperlipidemia. Please review and update either Med Hx or this indication to match' answered with 'Medical history term updated' (Site from CRA).	Steven Anderson (b) (4)	19 Oct 2020 20:18:20
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	19 Oct 2020 20:17:23
User entered 'Hyperlipidemia' reason for change:	Steven Anderson (b) (4)	19 Oct 2020 20:17:23
Data Entry Error	(b) (4)	
User opened query 'Med Hx term is hyperlipidemia. Please review and update either Med Hx or this indication to match' (Site from CRA).	(b) (4), (b) (6)	26 Sep 2020 12:48:07
DataPoint Verified.	(b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'dyslipdemia'	Jacob sekinger (b) (4)	02 Sep 2020 20:18:17
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '20'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'mg (mg)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'once daily (QD)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Oral (ORAL)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'un UNK 2010'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered '0'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered empty.	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Sep 2020 12:46:16
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 20:18:17

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	03 Nov 2020 19:49:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Nov 2020 19:49:24
Data point term sent to Coder Coding entries removed.	System Melissa Fuson (b) (4)	03 Nov 2020 19:33:01 03 Nov 2020 19:32:58
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE, PRODUCTSYNONYM: OZEMPIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:41:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 15:41:08
Data point term sent to Coder User entered 'OZEMPIC'	System Melissa Fuson (b) (4)	28 Sep 2020 15:40:06 28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'TYPE TWO DIABETES'	(b) (4) Melissa Fuson (b) (4)	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered '.25'	(b) (4) Melissa Fuson (b) (4)	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered 'mg (mg)'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered 'every week (QS)'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Subcutaneous). Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 10:21:13
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Subcutaneous). Please update route as appropriate.' answered with 'CHANGED PER DM CLR' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 19:33:14
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Nov 2020 19:32:58
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Subcutaneous). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Oct 2020 21:18:59
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4) (b) (4)	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered '8 Sep 2020'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	28 Sep 2020 15:39:53
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	28 Sep 2020 15:39:53

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:22:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 20:22:34
Data point term sent to Coder	System	19 Oct 2020 20:21:58
User entered 'Influenza Vaccine'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'Influenza Prophylactic'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'I'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'Other (OTHER)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'injection'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'once (ONCE)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'Intramuscular (INTRAMUSCULAR)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered '10 Oct 2020'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered '10 Oct 2020'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	19 Oct 2020 20:21:01

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: TUSSIN DM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 15:35:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 15:35:15
Data point term sent to Coder	System	26 Jan 2021 15:34:08
Coding entries removed.	Steven Anderson (b) (4)	26 Jan 2021 15:33:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:27
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: TUSSIN DM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:53:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 14:53:18
Data point term sent to Coder	System	24 Nov 2020 14:52:06
User entered 'TUSSIN DM'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:29
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:23:25
User closed query 'Per DM CLR: Please note that there is no AE matching the COUGH Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		27 Jan 2021 05:58:10
Query 'Per DM CLR: Please note that there is no AE matching the COUGH Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'this medication was taken for symptomatic COVID 19 ae' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:33:27
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:33:08
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Jan 2021 15:33:08
User opened query 'Per DM CLR: Please note that there is no AE matching the COUGH Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 11:01:17
DataPoint Verified.		01 Dec 2020 19:06:41
Query 'Per ETRTR, According to Adverse Events page, Concomitant Medication box is not checked. Please reconcile.' canceled (Site from CRA).		01 Dec 2020 19:06:38
User opened query 'Per ETRTR, According to Adverse Events page, Concomitant Medication box is not checked. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	26 Nov 2020 19:42:33
User entered 'COVID-19 (COUGH)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 06:00:54
Query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'dose has been updated to 10 ml' (Site from DM).	Steven Anderson (b) (4) (b) (4)	26 Jan 2021 15:32:38
User opened query 'Per DM CLR: Please provide the actual dose for this medication as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 09:16:58
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:06:12
User entered '10'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:13
User entered 'mL (mL)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:15
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:17
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:19
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:04:25
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:04:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:04:22
User entered '13 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:04
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:00
User closed query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		27 Jan 2021 05:58:51
Query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'stop date has been updated per source documents' (Site from DM).	Steven Anderson (b) (4)	26 Jan 2021 15:39:32
DataPoint Un-verified.	Steven Anderson (b) (4)	26 Jan 2021 15:39:12
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Jan 2021 15:39:12
User opened query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:01:39
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:04:20
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:02
DataPoint Un-verified.	Steven Anderson (b) (4)	26 Jan 2021 15:39:12
User entered '13 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	26 Jan 2021 15:39:12
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:06:02
User entered empty.	Melissa Fuson (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'not solicited - please update to No' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:06
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:24:04
Query 'not solicited - please update to No' answered with 'updated to NO per query.' (Site from CRA).	Melissa Fuson (b) (4)	03 Dec 2020 14:56:19
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4)	03 Dec 2020 14:55:38
User opened query 'not solicited - please update to No' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 19:10:45
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:39
User entered empty.	System	24 Nov 2020 14:51:23

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:13:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Jan 2021 00:13:55
Data point term sent to Coder	System	26 Jan 2021 15:40:13
Coding entries removed.	Steven Anderson (b) (4)	26 Jan 2021 15:39:58
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:06:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED [PSEUDOEPHEDRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 14:58:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 14:58:12
Data point term sent to Coder	System	24 Nov 2020 14:54:09
User entered 'SUDAFED (PSEUDOEPHEDRINE HCL)'	Melissa Fuson (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:06:58
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:26
User closed query 'Per DM CLR: Please note that there is no AE matching the NASAL CONGESTION Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).		27 Jan 2021 06:01:22
Query 'Per DM CLR: Please note that there is no AE matching the NASAL CONGESTION Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'term has been updated for symptomatic COVID 19 ' (Site from DM).	Steven Anderson (b) (4)	26 Jan 2021 15:40:31
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	26 Jan 2021 15:39:58
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	26 Jan 2021 15:39:58
User opened query 'Per DM CLR: Please note that there is no AE matching the NASAL CONGESTION Con Med indication during this time frame. Please review Con Med use, add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:02:26
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:06:59
User entered 'COVID-19 (NASAL CONGESTION'	Melissa Fuson (b) (4)	24 Nov 2020 14:53:14
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:10
User entered '30'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:11
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:13
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:17
User entered 'other (OTHER)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:20
User entered 'TWICE DAILY AS NEEDED'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:22
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:31
User entered '16 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:07:33
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:47
User closed query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		27 Jan 2021 06:01:31
Query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'end date has been updated as indicated in source' (Site from DM).	Steven Anderson (b) (4)	26 Jan 2021 15:41:15
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	26 Jan 2021 15:41:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	26 Jan 2021 15:41:01
User opened query 'Per DM CLR: After reviewing Con Med use, please confirm if a stop date should be recorded, only if the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 11:02:47
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:07:35
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	24 Nov 2020 14:53:14
	(b) (4)	

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:48
DataPoint Un-verified.	Steven Anderson (b) (4)	26 Jan 2021 15:41:01
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	26 Jan 2021 15:41:01
DataPoint Verified.	(b) (4), (b) (6)	01 Dec 2020 19:07:45
User entered empty.	Melissa Fuson (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:26:23
User closed query 'not solicited - please update to No' (Site from CRA).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 21:24:52
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 21:24:50
Query 'not solicited - please update to No' answered with 'updated per query' (Site from CRA).	Melissa Fuson (b) (4)	03 Dec 2020 14:56:46
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4)	03 Dec 2020 14:56:35
User opened query 'not solicited - please update to No' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 19:10:30
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User entered empty.	System	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User entered empty.	System	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:38:27

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:48:44
User entered empty.	System	24 Nov 2020 14:53:14

US3412304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:38:27

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:44:27
	(b) (4)	
User entered 'No (N)'	Jacob sekinger (b) (4)	02 Sep 2020 20:18:39
	(b) (4)	

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:38:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
User entered '11/Nov/2020 21:52'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:38:27

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 18:18:34
Reviewed for Safety.	(b) (4)	21 Nov 2020 00:35:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:37
User entered 'I'		11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:38:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
User entered '18/Nov/2020 17:16'	System	18 Nov 2020 22:16:32

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:38:27

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 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered '1'		18 Nov 2020 22:16:32

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:38:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 18:02:01
User entered '20/Nov/2020 19:35'	System	21 Nov 2020 00:35:43

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:38:27

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 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 03:41:29
DataPoint Verified.		21 Nov 2020 18:02:01
User entered '1'		21 Nov 2020 00:35:43

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4)	21 Nov 2020 00:35:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:38:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:33:45
User entered '02/Dec/2020 03:41'	System	02 Dec 2020 03:41:40

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:38:27

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 18:18:34
DataPoint Verified.	(b) (4)	09 Apr 2021 12:33:45
Reviewed for Safety.	(b) (4), (b) (6)	14 Dec 2020 15:11:51
User entered 'I'		02 Dec 2020 03:41:40

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'USA-US061-2020-MRNA-1273-P301000009'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4)	19 Nov 2020 17:35:37
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'No (N)'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gregory'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Gottschlich'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '4260 Glendale Milford Road'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered 'Cincinnati'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:35:37
Reviewed for Safety.		11 Nov 2020 21:51:38
User entered '45242'	System	11 Nov 2020 21:51:19

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:29
DataPoint Verified.		19 Nov 2020 17:35:37
User entered 'US'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 11 Aug 2021 22:38:27

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	14 Dec 2020 15:12:05
User entered '4'	System	02 Dec 2020 03:41:40
User entered '3'	System	21 Nov 2020 00:35:43
User entered '2'	System	18 Nov 2020 22:16:32
User entered '1'	System	11 Nov 2020 21:52:16

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:38:27

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 18:18:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:33:45
User entered '14/Dec/2020 10:12'	System	14 Dec 2020 15:12:05

US3412304

Folder: SAE USA-US061-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:38:27

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 18:18:34
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:33:45
User entered 'I'		14 Dec 2020 15:12:05