

US3952216 (Prod: Synexus - Optimal Research - Rockville)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:41:29

All time stamps listed in this document are displayed in GMT

US3952216

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Participant ID

US3952216

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

US3952216

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Date of Informed Consent (<i>dd MMM yyyy</i>)	09 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input checked="" type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 22:42:03

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Condition	ATTENTION DEFICIT HYPERACTIVITY DISORDER
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Condition	APPENDICITIS
Start date (dd MMM yyyy)	30 SEP 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	SEP 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	03 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	03 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:41 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:41
Height (<i>xxx.x</i>)	66.0 in
Weight (<i>xxx.x</i>)	245.0 lb
BMI (<i>xxx.x</i>)	39.62672 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 OCT 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*) 09 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	09 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:42:03

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify GROCERIES THREE TIMES WEEKLY.

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 22:42:03

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

What was the date of randomization? (dd MMM yyyy) 09 OCT 2020

What was the participant's randomization number? 116796

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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)	09 OCT 2020
Time of assessment (00:00-23:59)	09:41 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 09:41
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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)	09 OCT 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	09 OCT 2020 13:27
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)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	145 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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) 09 OCT 2020

What was the treatment time? (00:00-23:59) 11:50 (24 HR)

Treatment Date and Time (derived) 09 OCT 2020 11:50

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 OCT 2020

Collection time (00:00-23:59)

11:17 (24 HR)

Collection date and time (derived)

09 OCT 2020 11:17

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Collection date (dd MMM yyyy)			09 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:19	09 OCT 2020 11:19
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

09 OCT 2020 13:09

PC Open Date & Time

09 OCT 2020 12:10

PC Close Date & Time

09 OCT 2020 14:40

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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 98.7 °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	09 OCT 2020 21:36
PC Open Date & Time	09 OCT 2020 15:35
PC Close Date & Time	10 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

99.1 °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

10 OCT 2020 21:20

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 23:38

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

99.1 °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

12 OCT 2020 21:29

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

99.1 °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

13 OCT 2020 21:43

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

99.1 °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

15 OCT 2020 02:59

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 OCT 2020 21:02

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

09 OCT 2020 13:10

PC Open Date & Time

09 OCT 2020 12:10

PC Close Date & Time

09 OCT 2020 14:40

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

09 OCT 2020 21:34

PC Open Date & Time

09 OCT 2020 15:35

PC Close Date & Time

10 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

10

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 21:21

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

11 OCT 2020 23:40

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

12 OCT 2020 21:28

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

13 OCT 2020 21:42

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

15 OCT 2020 02:58

PC Open Date & Time

14 OCT 2020 12:00

PC Close Date & Time

15 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

15 OCT 2020 21:00

PC Open Date & Time

15 OCT 2020 12:00

PC Close Date & Time

16 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 13:10
PC Open Date & Time	09 OCT 2020 12:10
PC Close Date & Time	09 OCT 2020 14:40

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

No ☒

Yes ☐

PC Time stamp	09 OCT 2020 21:33
PC Open Date & Time	09 OCT 2020 15:35
PC Close Date & Time	10 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

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 ☒

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 21:19
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 23:39
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

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 ☒

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 21:28
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

54 of 2228

EAB) (1725)

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 21:41
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

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 ☒

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

Yes <input type="checkbox"/>	
PC Time stamp	15 OCT 2020 02:57
PC Open Date & Time	14 OCT 2020 12:00
PC Close Date & Time	15 OCT 2020 11:59

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

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 ☒

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	06 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	VISIT2

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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)	06 NOV 2020
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 09:31
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	105 mmHg
Diastolic Blood Pressure units	MMHG

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	

US3952216

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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.

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 06 NOV 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

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?

What was the treatment date? (dd MMM yyyy)

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

Treatment Date and Time (derived)

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

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3952216

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

06 NOV 2020

Collection time (00:00-23:59)

10:11 (24 HR)

Collection date and time (derived)

06 NOV 2020 10:11

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Collection date (dd MMM yyyy)			06 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:06	06 NOV 2020 10:06
Nasopharyngeal Swab 2	No		

US3952216

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:54:18

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:54:18

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:03

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 22:42:04

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 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	VISIT3

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 22:42:04

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 DEC 2020
Time of assessment (00:00-23:59)	13:36 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 13:36
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)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952216

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 22:42:04

Generated On: 12 Aug 2021 13:41:29

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.

US3952216

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 22:42:04

Generated On: 12 Aug 2021 13:41:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

03 DEC 2020

Collection time (00:00-23:59)

13:48 (24 HR)

Collection date and time (derived)

03 DEC 2020 13:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 22:42:04

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 12:35:29

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 DEC 2020 00:47:03
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 09:55:33
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 11:09:47
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 23:58:43

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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	11 JAN 2021 09:56:43
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 10:27:42

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 18:00:25
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

31 JAN 2021 00:58:15

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 00:01:40
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 FEB 2021 00:02:16
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

21 FEB 2021 19:56:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

28 FEB 2021 15:23:22

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

09 MAR 2021 12:00:44

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

14 MAR 2021 00:02:32

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 MAR 2021 17:10:38

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 11:39:21

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:02:36

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

11 APR 2021 01:08:06

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 00:26:03

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 01:11:33

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

02 MAY 2021 01:56:47

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 236

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 264

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 271

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐ Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐
Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐ Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐
Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐ Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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17 FEB 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

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

Date and time of submission

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13 MAR 2022 00:01

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17 MAR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

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24 MAR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 614

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 ☐
Yes ☐

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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°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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 <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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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°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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 733

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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 <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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

17 NOV 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

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

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3952216

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:41:29

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		28 FEB 2021 15:22:59

US3952216

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 21:54:18

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 21:54:18

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:05

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952216

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3952216

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

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.

US3952216

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

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

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

US3952216

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Date of Contact	12 FEB 2021
Time of Contact	20:00
Date and Time of Contact (derived)	12 FEB 2021 20:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" 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>

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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"/>

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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"/>

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (11)

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Form: Symptom Log (12)

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (12)

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

Symptom Day

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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"/>

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	37.4 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

	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"/>

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Data signed: (b) (4) 09 Apr 2021 20:19:13

Generated On: 12 Aug 2021 13:41:29

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 ☐

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Date of Visit	26 FEB 2021
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 type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 FEB 2021
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)	0

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Folder: Covid-19 Assessment 12 Feb 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 16:34:34

Generated On: 12 Aug 2021 13:41:29

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 FEB 2021
Day 5	Yes	02 MAR 2021
Day 7	Yes	04 MAR 2021
Day 9	No	
Day 14	Yes	11 MAR 2021
Day 21	Yes	18 MAR 2021
Day 28	No	

US3952216

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD1

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	26 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	15:51 (24 HR)
Vital Signs Date and Time (derived)	26 FEB 2021 15:51
Height (<i>xxx.x</i>)	66.0 in
Weight (<i>xxx.x</i>)	266.0 lb
Temperature (<i>xxx.x</i>)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	92 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	99 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952216

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 FEB 2021

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

US3952216

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 FEB 2021

US3952216

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3952216

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (<i>dd MMM yyyy</i>)	
Time of assessment (<i>00:00-23:59</i>)	
Vital Signs Date and Time (derived)	
Temperature (<i>xxx.x</i>)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (<i>xxx</i>)	
Pulse units	
Respiratory Rate (<i>xxx</i>)	
Respiratory Rate units	
Systolic Blood Pressure (<i>xxx</i>)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (<i>xxx</i>)	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	

US3952216

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

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.

US3952216

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:41:29

Was Blood Sample Taken for Immunologic Assessment of	Yes	<input type="checkbox"/>
SARS_COV-2 Infection?	No	<input type="checkbox"/>
	NA (COVID-19 Negative)	<input type="checkbox"/>

Date of Collection	
--------------------	--

US3952216

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

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

Visit date (dd MMM yyyy)	04 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3952216

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	04 FEB 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3952216

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Height	66.0 in
Weight	255.0 lb
BMI (xxx.x)	41.24413

US3952216

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Height	66.0 in
Weight	255.0 lb
BMI (xxx.x)	41.24413
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	10:23 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:23
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	119 mmHg
Diastolic Blood Pressure units	MMHG

US3952216

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Height	66.0 in
Weight	255.0 lb
BMI (xxx.x)	41.24413
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 FEB 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 13:46
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	102 mmHg
Diastolic Blood Pressure units	MMHG

US3952216

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 FEB 2021

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

US3952216

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

Form: Pregnancy Test

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 04 FEB 2021

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

Collection date _____
Collection time _____
Collection date and time (derived) _____

US3952216

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

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) 04 FEB 2021

What was the treatment time? (00:00-23:59) 12:29 (24 HR)

Treatment Date and Time (derived) 04 FEB 2021 12:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3952216

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 FEB 2021

Collection time (00:00-23:59)

09:42 (24 HR)

Collection date and time (derived)

04 FEB 2021 09:42

US3952216

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

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

Collection date (dd MMM yyyy)	04 FEB 2021
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Collection time (00:00 - 23:59)	12:29
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Collection Date and Time (derived)	04 FEB 2021 12:29
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US3952216

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

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3952216

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3952216

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

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

US3952216

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	05 APR 2021
Time of assessment (<i>00:00-23:59</i>)	09:50 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 09:50
Temperature (<i>xxx.x</i>)	37.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	80 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	98 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952216

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3952216

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	05 APR 2021
Collection time (<i>00:00-23:59</i>)	10:42 (24 HR)
Collection date and time (derived)	05 APR 2021 10:42

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Visit Date	04 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:44 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 10:44
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	94 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Visit Date	04 FEB 2021
Please check all assessments that apply for this visit	
Physical Exam	False
Vital Signs	True
Immunogenicity Assessment	False
Pregnancy Test	False

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 20:43:19

Generated On: 12 Aug 2021 13:41:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	11:47 (24 HR)
Vital Signs Date and Time (derived)	04 FEB 2021 11:47
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	91 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	101 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3952216

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 19:15:12

Generated On: 12 Aug 2021 13:41:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

AEID	
Adverse event	HYPERTENSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	16 OCT 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)	06 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

AEID

Adverse event

HYPERTENSION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

06 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☐

Grade 3/Severe ☒

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input checked="" type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

AEID	
Adverse event	COUGH
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	06 FEB 2021
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)	25 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 20:22:10

Generated On: 12 Aug 2021 13:41:29

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

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

Yes ☒

No ☐

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

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Name of Medication ADDERALL ER

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT
HYPERACTIVITY DISORDER

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

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

	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 1996
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"/>

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Name of Medication NEXPLANON

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 68

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

EVERY FIVE YEARS

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

	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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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)

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US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

	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)	17 OCT 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 type="radio"/>
	804	<input checked="" type="radio"/>

US3952216

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 20:43:03

Generated On: 12 Aug 2021 13:41:29

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3952216

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 08 Apr 2021 20:43:04

Generated On: 12 Aug 2021 13:41:29

Date of dosing discontinuation (dd MMM yyyy) 06 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	<input checked="" type="radio"/>
SAE (specify)	<input type="radio"/>
Death	<input type="radio"/>
Lost To Follow-up	<input type="radio"/>
Physician decision (specify)	<input type="radio"/>
Pregnancy	<input type="radio"/>
Protocol deviation (specify)	<input type="radio"/>
Study Terminated By Sponsor	<input type="radio"/>
Withdrawal of consent by participant (specify)	<input type="radio"/>
Due to SARS-COV-2	<input type="radio"/>
Other	<input type="radio"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify #2

US3952216

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:41:29

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 ☐

Audit

US3952216 (Prod: Synexus - Optimal Research - Rockville)

US3952216

Form: Participant Creation

Generated On: 12 Aug 2021 13:41:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'US3952216'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	09 Oct 2020 13:57:46

US3952216

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 20:24:39

US3952216

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 13:57:48

US3952216

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Clinic (Clinic)'	Nick Bart (b) (4)	13 Oct 2020 20:24:39

US3952216

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'SCRN'	System	13 Oct 2020 20:24:39

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 13:57:48

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '31'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'YEARS'	System	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '31'	System	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Female (F)'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'I'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:41:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:07

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Oct 2020'	System	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2020'	System	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Amendment 4 (4)' reason for change:	(b) (4)	
Data Entry Error	Atanas Filev (b) (4)	09 Oct 2020 17:00:14
User entered 'Amendment 3 (3)'	(b) (4)	
	Atanas Filev (b) (4)	09 Oct 2020 17:00:10
	(b) (4)	

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Atanas Filev (b) (4)	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:10

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 13:57:48

US3952216

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:41:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'I'	System	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:41:29

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:41:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:27:29

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit/hyperactivity disorder - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 20:30:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:30:27
Data point term sent to Coder	System	13 Oct 2020 20:28:42
User entered 'attention deficit hyperactivity disorder'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'un UNK 1995'	Nick Bart (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Jan 1995'	System	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '1995'	System	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered empty.	System	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:41:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered empty.	System	13 Oct 2020 20:28:03

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 20:30:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:30:28
Data point term sent to Coder	System	13 Oct 2020 20:29:44
User entered 'obesity'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'un UNK 2014'	Nick Bart (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Jan 2014'	System	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2014'	System	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered empty.	System	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:41:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered empty.	System	13 Oct 2020 20:29:18

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:56:28
Data point term sent to Coder	System	13 Oct 2020 20:55:54
User entered 'appendicitis'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '30 Sep 2019'	Nick Bart (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Oct 2019'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Sep 2019'	System	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2019'	System	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Oct 2019'	System	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:41:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2019'	System	13 Oct 2020 20:55:52

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 20:57:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 20:57:18
Data point term sent to Coder	System	13 Oct 2020 20:56:54
User entered 'appendectomy'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Oct 2019'	Nick Bart (b) (4)	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Oct 2019'	Nick Bart (b) (4)	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Oct 2019'	System	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2019'	System	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'Oct 2019'	System	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:41:29

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '2019'	System	13 Oct 2020 20:56:10

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09:41'	Nick Bart (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '09 Oct 2020 09:41'	System	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '66.0' in	Nick Bart (b) (4)	13 Oct 2020 20:27:14
DataPoint set to visible.	System	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '245.0' lb	Nick Bart (b) (4)	13 Oct 2020 20:27:14
DataPoint set to visible.	System	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered '39.62672'	System	13 Oct 2020 20:27:14
DataPoint set to visible.	System	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'kg/m2'	System	13 Oct 2020 20:27:14
DataPoint set to visible.	System	09 Oct 2020 17:00:19

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	Nick Bart (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'bpm'	System	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'breaths/min'	System	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'mmHg'	System	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered 'mmHg'	System	13 Oct 2020 20:27:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14

US3952216

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 18:34:14

US3952216

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:24:55

US3952216

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4) System	13 Oct 2020 20:25:02
User entered '09 Oct 2020' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:25:02
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	13 Oct 2020 20:24:55
User entered empty.	Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:24:55

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4)	13 Oct 2020 20:26:34
	Nick Bart (b) (4)	
	(b) (4)	

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Childbearing Potential

Generated On: 12 Aug 2021 13:41:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:26:34

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Urine (URINE)'	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Negative (NEGATIVE)'	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User entered empty.	System	13 Oct 2020 20:26:44

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'groceries three times weekly.'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

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 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'I'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:41:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:34:14
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:24:31

US3952216

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:25

US3952216

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:25

US3952216

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:25

US3952216

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'VISIT1'	System	13 Oct 2020 20:57:25

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:32:45

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '116796'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:32:45

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Oct 2020 15:32:45

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

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)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

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)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35

US3952216

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:41:29

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:35
DataPoint set to visible.	System	09 Oct 2020 17:00:10

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09:41'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '09 Oct 2020 09:41'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	13 Oct 2020 21:00:36
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	13 Oct 2020 21:00:36
User entered '37.1' C reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:00:36
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	13 Oct 2020 21:00:28
User entered '7.1' C	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '84'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'bpm'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:55:27
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 18:23:02
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:01:17
User entered '20'	Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'breaths/min'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '139'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'mmHg'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:55:29
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4) (b) (4)	03 Nov 2020 18:23:06
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:01:31
User entered '99'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'mmHg'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '13:27'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '09 Oct 2020 13:27'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '37.1' C	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '66'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'bpm'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '16'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'breaths/min'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 11:55:36
Query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	03 Nov 2020 18:23:17
User opened query 'Per CDM: Per CCG V2.0 page 50, SBP ≤ 89 or ≥ 141 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:02:03
User entered '145'	Nick Bart (b) (4)	13 Oct 2020 21:00:28

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'mmHg'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Nov 2020 11:55:38
Query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' answered with 'NCS' (Site from DM).	Nick Bart (b) (4) (b) (4)	03 Nov 2020 18:23:21
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP \geq 91 mmHg is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 05:02:19
User entered '100'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'mmHg'	System	13 Oct 2020 21:00:28

US3952216

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:40

US3952216

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:40

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered empty.	System	13 Oct 2020 20:57:52

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

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)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'MRNA-1273 OR PLACEBO'	System	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '11:50'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '09 Oct 2020 11:50'	System	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Left Arm (LEFT ARM)'	(b) (4) Atanas Filev (b) (4) (b) (4)	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'ONCE'	System	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'INTRAMUSCULAR'	System	09 Oct 2020 17:00:45

US3952216

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:54

US3952216

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:00:54

US3952216

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '11:17'	Nick Bart (b) (4)	13 Oct 2020 21:00:54

US3952216

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '09 Oct 2020 11:17'	System	13 Oct 2020 21:00:54

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09 Oct 2020'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '11:19'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '09 Oct 2020 11:19'	System	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered empty.	System	13 Oct 2020 21:01:08

US3952216

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	13 Oct 2020 20:57:44

US3952216

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered '1'	System	13 Oct 2020 20:57:44

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:09:32', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fff5a6a8-8b1c-4a46-8429-d51330dffd65' User entered 'Yes (Y)'	System	09 Oct 2020 17:09:56
	System	09 Oct 2020 17:09:56

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:09:39', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fff5a6a8-8b1c-4a46-8429-d51330dffd65' User entered '98.0'	System	09 Oct 2020 17:09:56
	System	09 Oct 2020 17:09:56

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:09:43', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fff5a6a8-8b1c-4a46-8429-d51330dffd65'	System	09 Oct 2020 17:09:56
User entered 'No (N)'	System	09 Oct 2020 17:09:56

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:09:52', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fff5a6a8-8b1c-4a46-8429-d51330dffd65' User entered '09 Oct 2020 13:09'	System	09 Oct 2020 17:09:56
	System	09 Oct 2020 17:09:56

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '09 Oct 2020 12:10'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '09 Oct 2020 14:40'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:36:09', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'c18906b7-0d39-468d-8171-4f538b865499' User entered 'Yes (Y)'	System	10 Oct 2020 01:36:37
	System	10 Oct 2020 01:36:37

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:36:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'c18906b7-0d39-468d-8171-4f538b865499' User entered '98.7'	System	10 Oct 2020 01:36:37
	System	10 Oct 2020 01:36:37

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:36:29', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'c18906b7-0d39-468d-8171-4f538b865499'	System	10 Oct 2020 01:36:37
User entered 'No (N)'	System	10 Oct 2020 01:36:37

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:36:34', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'c18906b7-0d39-468d-8171-4f538b865499'	System	10 Oct 2020 01:36:37
User entered '09 Oct 2020 21:36'	System	10 Oct 2020 01:36:37

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 2'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:20:06', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '39567b5d-364f-4663-bc7a-62776874ef61' User entered 'Yes (Y)'	System	11 Oct 2020 01:20:26
	System	11 Oct 2020 01:20:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:20:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '39567b5d-364f-4663-bc7a-62776874ef61' User entered '99.1'	System	11 Oct 2020 01:20:26
	System	11 Oct 2020 01:20:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:20:11', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '39567b5d-364f-4663-bc7a-62776874ef61' User entered 'No (N)'	System	11 Oct 2020 01:20:26
	System	11 Oct 2020 01:20:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:20:23', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '39567b5d-364f-4663-bc7a-62776874ef61' User entered '10 Oct 2020 21:20'	System	11 Oct 2020 01:20:26
	System	11 Oct 2020 01:20:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 3'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:30', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96e0a4d3-b401-45b7-a13e-8062c5f1f16e' User entered 'Yes (Y)'	System	12 Oct 2020 03:38:49
	System	12 Oct 2020 03:38:49

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96e0a4d3-b401-45b7-a13e-8062c5f1f16e' User entered '99.1'	System	12 Oct 2020 03:38:49
	System	12 Oct 2020 03:38:49

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96e0a4d3-b401-45b7-a13e-8062c5f1f16e' User entered 'No (N)'	System	12 Oct 2020 03:38:49
	System	12 Oct 2020 03:38:49

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:47', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96e0a4d3-b401-45b7-a13e-8062c5f1f16e' User entered '11 Oct 2020 23:38'	System	12 Oct 2020 03:38:49
	System	12 Oct 2020 03:38:49

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 4'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:45', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fd7de424-a758-424e-b6ba-706eccadc095' User entered 'Yes (Y)'	System	13 Oct 2020 01:29:14
	System	13 Oct 2020 01:29:14

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:51', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fd7de424-a758-424e-b6ba-706eccadc095' User entered '99.1'	System	13 Oct 2020 01:29:14
	System	13 Oct 2020 01:29:14

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:55', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fd7de424-a758-424e-b6ba-706eccadc095'	System	13 Oct 2020 01:29:14
User entered 'No (N)'	System	13 Oct 2020 01:29:14

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:29:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'fd7de424-a758-424e-b6ba-706eccadc095'	System	13 Oct 2020 01:29:14
User entered '12 Oct 2020 21:29'	System	13 Oct 2020 01:29:14

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 5'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:50', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b8ec178d-005c-4541-9650-76764ce04662' User entered 'Yes (Y)'	System	14 Oct 2020 01:43:05
	System	14 Oct 2020 01:43:05

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:55', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b8ec178d-005c-4541-9650-76764ce04662' User entered '99.1'	System	14 Oct 2020 01:43:05
	System	14 Oct 2020 01:43:05

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:59', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b8ec178d-005c-4541-9650-76764ce04662'	System	14 Oct 2020 01:43:05
User entered 'No (N)'	System	14 Oct 2020 01:43:05

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:43:01', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b8ec178d-005c-4541-9650-76764ce04662' User entered '13 Oct 2020 21:43'	System	14 Oct 2020 01:43:05
	System	14 Oct 2020 01:43:05

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 6'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:58:10', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2786a579-1bfd-47ce-a052-0555bb7b5fab' User entered 'Yes (Y)'	System	15 Oct 2020 06:59:26
	System	15 Oct 2020 06:59:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:59:10', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2786a579-1bfd-47ce-a052-0555bb7b5fab' User entered '99.1'	System	15 Oct 2020 06:59:26
	System	15 Oct 2020 06:59:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:59:13', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2786a579-1bfd-47ce-a052-0555bb7b5fab' User entered 'No (N)'	System	15 Oct 2020 06:59:26
	System	15 Oct 2020 06:59:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:59:23', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2786a579-1bfd-47ce-a052-0555bb7b5fab' User entered '15 Oct 2020 02:59'	System	15 Oct 2020 06:59:26
	System	15 Oct 2020 06:59:26

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 7'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:01:47', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '34d76bd5-24b9-4d56-9dd5-cd5e330e9164' User entered 'Yes (Y)'	System	16 Oct 2020 01:02:50
	System	16 Oct 2020 01:02:50

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:02:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '34d76bd5-24b9-4d56-9dd5-cd5e330e9164' User entered '99.3'	System	16 Oct 2020 01:02:50
	System	16 Oct 2020 01:02:50

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:02:44', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '34d76bd5-24b9-4d56-9dd5-cd5e330e9164'	System	16 Oct 2020 01:02:50
User entered 'No (N)'	System	16 Oct 2020 01:02:50

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:02:48', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '34d76bd5-24b9-4d56-9dd5-cd5e330e9164'	System	16 Oct 2020 01:02:50
User entered '15 Oct 2020 21:02'	System	16 Oct 2020 01:02:50

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:51:07
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:01', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f9c7f72e-bbbe-46cf-8727-d4bd57e73a41'	System	09 Oct 2020 17:10:26
User entered 'None (1)'	System	09 Oct 2020 17:10:26

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:05', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f9c7f72e-bbbe-46cf-8727-d4bd57e73a41' User entered 'No (N)'	System	09 Oct 2020 17:10:26
	System	09 Oct 2020 17:10:26

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:13', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f9c7f72e-bbbe-46cf-8727-d4bd57e73a41' User entered 'No (N)'	System	09 Oct 2020 17:10:26
	System	09 Oct 2020 17:10:26

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f9c7f72e-bbbe-46cf-8727-d4bd57e73a41' User entered 'None (1)'	System	09 Oct 2020 17:10:26
	System	09 Oct 2020 17:10:26

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f9c7f72e-bbbe-46cf-8727-d4bd57e73a41' User entered '09 Oct 2020 13:10'	System	09 Oct 2020 17:10:26
	System	09 Oct 2020 17:10:26

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 12:10'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 14:40'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:34:04', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '91162b99-11b3-494c-b99d-73719c5b5454'	System	10 Oct 2020 01:34:24
User entered 'Does not interfere with activity (2)'	System	10 Oct 2020 01:34:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:34:08', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '91162b99-11b3-494c-b99d-73719c5b5454'	System	10 Oct 2020 01:34:24
User entered 'No (N)'	System	10 Oct 2020 01:34:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:34:11', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '91162b99-11b3-494c-b99d-73719c5b5454' User entered 'No (N)'	System	10 Oct 2020 01:34:24
	System	10 Oct 2020 01:34:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:34:14', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '91162b99-11b3-494c-b99d-73719c5b5454' User entered 'None (1)'	System	10 Oct 2020 01:34:24
	System	10 Oct 2020 01:34:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:34:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '91162b99-11b3-494c-b99d-73719c5b5454' User entered '09 Oct 2020 21:34'	System	10 Oct 2020 01:34:24
	System	10 Oct 2020 01:34:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 2'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:04', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7'	System	11 Oct 2020 01:21:34
User entered 'Does not interfere with activity (2)'	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:07', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7' User entered 'No (N)'	System	11 Oct 2020 01:21:34
	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:10', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7' User entered 'Yes (Y)'	System	11 Oct 2020 01:21:34
	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7' User entered '10'	System	11 Oct 2020 01:21:34
	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:26', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7' User entered 'None (1)'	System	11 Oct 2020 01:21:34
	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:21:32', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '27afcd90-d919-48fa-9ccd-9e86daf471a7' User entered '10 Oct 2020 21:21'	System	11 Oct 2020 01:21:34
	System	11 Oct 2020 01:21:34

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 3'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:31', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '95917eb7-f605-4ef2-bf9d-0fb1b303f78b'	System	12 Oct 2020 03:40:07
User entered 'Does not interfere with activity (2)'	System	12 Oct 2020 03:40:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:33', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '95917eb7-f605-4ef2-bf9d-0fb1b303f78b' User entered 'No (N)'	System	12 Oct 2020 03:40:07
	System	12 Oct 2020 03:40:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:52', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '95917eb7-f605-4ef2-bf9d-0fb1b303f78b' User entered 'No (N)'	System	12 Oct 2020 03:40:07
	System	12 Oct 2020 03:40:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:59', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '95917eb7-f605-4ef2-bf9d-0fb1b303f78b' User entered 'None (1)'	System	12 Oct 2020 03:40:07
	System	12 Oct 2020 03:40:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:40:05', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '95917eb7-f605-4ef2-bf9d-0fb1b303f78b' User entered '11 Oct 2020 23:40'	System	12 Oct 2020 03:40:07
	System	12 Oct 2020 03:40:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 4'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b33f18ce-7e17-446a-af29-58fe7b2996d4'	System	13 Oct 2020 01:28:42
User entered 'Does not interfere with activity (2)'	System	13 Oct 2020 01:28:42

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b33f18ce-7e17-446a-af29-58fe7b2996d4'	System	13 Oct 2020 01:28:42
User entered 'No (N)'	System	13 Oct 2020 01:28:42

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:31', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b33f18ce-7e17-446a-af29-58fe7b2996d4'	System	13 Oct 2020 01:28:42
User entered 'No (N)'	System	13 Oct 2020 01:28:42

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:34', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b33f18ce-7e17-446a-af29-58fe7b2996d4'	System	13 Oct 2020 01:28:42
User entered 'None (1)'	System	13 Oct 2020 01:28:42

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b33f18ce-7e17-446a-af29-58fe7b2996d4'	System	13 Oct 2020 01:28:42
User entered '12 Oct 2020 21:28'	System	13 Oct 2020 01:28:42

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 5'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:06', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17ba726e-780a-404b-95cb-62062a52e5b1' User entered 'None (1)'	System	14 Oct 2020 01:42:24
	System	14 Oct 2020 01:42:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:11', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17ba726e-780a-404b-95cb-62062a52e5b1' User entered 'No (N)'	System	14 Oct 2020 01:42:24
	System	14 Oct 2020 01:42:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:14', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17ba726e-780a-404b-95cb-62062a52e5b1' User entered 'No (N)'	System	14 Oct 2020 01:42:24
	System	14 Oct 2020 01:42:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17ba726e-780a-404b-95cb-62062a52e5b1' User entered 'None (1)'	System	14 Oct 2020 01:42:24
	System	14 Oct 2020 01:42:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:42:20', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17ba726e-780a-404b-95cb-62062a52e5b1' User entered '13 Oct 2020 21:42'	System	14 Oct 2020 01:42:24
	System	14 Oct 2020 01:42:24

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 6'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:53', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f7e0c4a6-9612-4b12-b4ba-b218a088be14' User entered 'None (1)'	System	15 Oct 2020 06:58:07
	System	15 Oct 2020 06:58:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:55', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f7e0c4a6-9612-4b12-b4ba-b218a088be14' User entered 'No (N)'	System	15 Oct 2020 06:58:07
	System	15 Oct 2020 06:58:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:58', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f7e0c4a6-9612-4b12-b4ba-b218a088be14' User entered 'No (N)'	System	15 Oct 2020 06:58:07
	System	15 Oct 2020 06:58:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:58:01', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f7e0c4a6-9612-4b12-b4ba-b218a088be14' User entered 'None (1)'	System	15 Oct 2020 06:58:07
	System	15 Oct 2020 06:58:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:58:03', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f7e0c4a6-9612-4b12-b4ba-b218a088be14' User entered '15 Oct 2020 02:58'	System	15 Oct 2020 06:58:07
	System	15 Oct 2020 06:58:07

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 7'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:39', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2e22c428-33a1-4c1c-8d99-8645c6853b50' User entered 'None (1)'	System	16 Oct 2020 01:00:53
	System	16 Oct 2020 01:00:53

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2e22c428-33a1-4c1c-8d99-8645c6853b50' User entered 'No (N)'	System	16 Oct 2020 01:00:53
	System	16 Oct 2020 01:00:53

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:44', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2e22c428-33a1-4c1c-8d99-8645c6853b50' User entered 'No (N)'	System	16 Oct 2020 01:00:53
	System	16 Oct 2020 01:00:53

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:47', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2e22c428-33a1-4c1c-8d99-8645c6853b50' User entered 'None (1)'	System	16 Oct 2020 01:00:53
	System	16 Oct 2020 01:00:53

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:50', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2e22c428-33a1-4c1c-8d99-8645c6853b50' User entered '15 Oct 2020 21:00'	System	16 Oct 2020 01:00:53
	System	16 Oct 2020 01:00:53

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:31', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:34', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:36', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:37', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:43', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'None (0)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:48', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered 'No (N)'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T13:10:50', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '71a2d85a-100f-4f50-bdc0-3e10a0caa9b4' User entered '09 Oct 2020 13:10'	System	09 Oct 2020 17:10:55
	System	09 Oct 2020 17:10:55

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 12:10'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 14:40'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 1, after vaccination (at home)'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:32', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:35', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:39', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:44', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:46', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'None (0)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:50', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered 'No (N)'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-09T21:33:53', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'f81efa56-9c30-49ad-9513-f597485707ad' User entered '09 Oct 2020 21:33'	System	10 Oct 2020 01:33:57
	System	10 Oct 2020 01:33:57

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '09 Oct 2020 15:35'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '10 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 2'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:05', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'None (0)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:08', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'None (0)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'None (0)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:23', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87'	System	11 Oct 2020 01:19:51
User entered 'Some interference with activity (2)'	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'None (0)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:28', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'None (0)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:41', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered 'No (N)'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-10T21:19:49', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e2627367-34a0-42e9-9b53-1bce17744e87' User entered '10 Oct 2020 21:19'	System	11 Oct 2020 01:19:51
	System	11 Oct 2020 01:19:51

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '10 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '11 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 3'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:52', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'None (0)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:54', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'None (0)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:38:57', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'None (0)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:06', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859'	System	12 Oct 2020 03:39:26
User entered 'No interference with activity (1)'	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:09', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'None (0)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:11', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'None (0)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered 'No (N)'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-11T23:39:24', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '8640564c-cc0d-4332-8606-a622dffe2859' User entered '11 Oct 2020 23:39'	System	12 Oct 2020 03:39:26
	System	12 Oct 2020 03:39:26

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '11 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '12 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 4'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:27:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:27:58', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:01', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:04', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:05', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:07', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'None (0)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:09', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered 'No (N)'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-12T21:28:12', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '528e02f9-2cc9-4657-a256-f610719a995a' User entered '12 Oct 2020 21:28'	System	13 Oct 2020 01:28:16
	System	13 Oct 2020 01:28:16

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '12 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '13 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 5'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:28', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:30', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:33', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:35', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:37', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'None (0)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:52', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered 'No (N)'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-13T21:41:54', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7fb4207b-ccad-4dae-bacd-86646efdf939' User entered '13 Oct 2020 21:41'	System	14 Oct 2020 01:42:04
	System	14 Oct 2020 01:42:04

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '13 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '14 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 6'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:32', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:35', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:37', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:40', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'None (0)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered 'No (N)'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T02:57:45', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b747cc45-7ec6-443d-b6cd-a44902302c18' User entered '15 Oct 2020 02:57'	System	15 Oct 2020 06:57:46
	System	15 Oct 2020 06:57:46

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '14 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '15 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
Data entry locked.	System	09 Oct 2020 17:00:45
User entered 'Day 7'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:20', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:24', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:26', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:28', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:30', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'None (0)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

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)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:33', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered 'No (N)'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-10-15T21:00:35', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '068d39b5-acd7-4da6-ad0e-ae7f48b1d2af' User entered '15 Oct 2020 21:00'	System	16 Oct 2020 01:00:44
	System	16 Oct 2020 01:00:44

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '15 Oct 2020 12:00'	System	09 Oct 2020 17:00:45

US3952216

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:41:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 02:50:17
User entered '16 Oct 2020 11:59'	System	09 Oct 2020 17:00:45

US3952216

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:07:26

US3952216

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '16 Oct 2020'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:07:26

US3952216

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:07:26

US3952216

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:07:26

US3952216

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:07:34

US3952216

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:59:21
User entered 'I'	System	21 Oct 2020 15:07:34

US3952216

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:00:52

US3952216

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '23 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:00:52

US3952216

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:00:52

US3952216

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:00:52

US3952216

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:00:55

US3952216

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 12:57:46
User entered 'I'	System	27 Oct 2020 14:00:55

US3952216

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	30 Oct 2020 20:42:16

US3952216

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '30 Oct 2020'	Stephanie Melton (b) (4)	30 Oct 2020 20:42:16

US3952216

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Stephanie Melton (b) (4) (b) (4)	30 Oct 2020 20:42:16

US3952216

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Stephanie Melton (b) (4)	30 Oct 2020 20:42:16

US3952216

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	Stephanie Melton (b) (4)	30 Oct 2020 20:42:21

US3952216

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 22:35:27
User entered 'I'	System	30 Oct 2020 20:42:21

US3952216

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'PER CDM: Please complete the Exposure form as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:38:55
Query 'PER CDM: Please complete the Exposure form as appropriate. Thank you.' answered with 'complete' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:48:26
User opened query 'PER CDM: Please complete the Exposure form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:49:40
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	11 Nov 2020 14:09:36

US3952216

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '06 Nov 2020'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:09:36

US3952216

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[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 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:09:36

US3952216

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'VISIT2'	System	11 Nov 2020 14:09:36

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '06 Nov 2020'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '09:31'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '06 Nov 2020 09:31'	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '37.2' C	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '84'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'bpm'	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:39:11
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 18:49:07
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:52:24
User entered '18'	Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'breaths/min'	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '138'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 50, DBP> 100 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:39:16
Query 'Per CDM: Per CCG V2.0 page 50, DBP> 100 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'CS. AE reported' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:49:05
User opened query 'Per CDM: Per CCG V2.0 page 50, DBP> 100 mmHg is considered as grade 3. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 18:52:56
User entered '105'	Nick Bart (b) (4) (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4) (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:13:02

US3952216

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:09:45

US3952216

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:09:45

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '06 Nov 2020'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Urine (URINE)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Negative (NEGATIVE)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:10:09

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	04 Jan 2021 18:46:50

US3952216

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:11:46

US3952216

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 06NOV2020. However, test result date is missing in GCL. Please confirm if 06NOV2020. is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Jan 2021 11:37:01
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 06NOV2020. However, test result date is missing in GCL. Please confirm if 06NOV2020. is correct date to update in GCL records.' answered with 'confirmed' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:46:14
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit 2 Day 29 is recorded as 06NOV2020. However, test result date is missing in GCL. Please confirm if 06NOV2020. is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 09:29:15
User entered '06 Nov 2020'	Nick Bart (b) (4) (b) (4)	11 Nov 2020 14:11:46

US3952216

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '10:11'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:11:46

US3952216

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '06 Nov 2020 10:11'	System	11 Nov 2020 14:11:46

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '06 Nov 2020'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '10:06'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '06 Nov 2020 10:06'	System	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	11 Nov 2020 14:12:03

US3952216

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	11 Nov 2020 14:09:40

US3952216

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '1'	System	11 Nov 2020 14:09:40

US3952216

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	14 Nov 2020 18:13:16

US3952216

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered '14 Nov 2020'	Brianne Okunji (b) (4)	14 Nov 2020 18:13:16

US3952216

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	14 Nov 2020 18:13:16

US3952216

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered empty.	Brianne Okunji (b) (4)	14 Nov 2020 18:13:16

US3952216

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	14 Nov 2020 18:13:28

US3952216

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'I'	System	14 Nov 2020 18:13:28

US3952216

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	Brianne Okunji (b) (4)	30 Nov 2020 23:31:56

US3952216

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '24 Nov 2020'	Brianne Okunji (b) (4)	30 Nov 2020 23:31:56

US3952216

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	30 Nov 2020 23:31:56

US3952216

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Brianne Okunji (b) (4)	30 Nov 2020 23:31:56

US3952216

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	30 Nov 2020 23:32:02

US3952216

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'I'	System	30 Nov 2020 23:32:02

US3952216

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	30 Nov 2020 23:33:02

US3952216

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '30 Nov 2020'	Brianne Okunji (b) (4)	30 Nov 2020 23:33:02

US3952216

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Contact Made (CONTACT MADE)'	Brianne Okunji (b) (4)	30 Nov 2020 23:33:02

US3952216

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	Brianne Okunji (b) (4)	30 Nov 2020 23:33:02

US3952216

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Brianne Okunji (b) (4) (b) (4)	30 Nov 2020 23:33:12

US3952216

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'I'	System	30 Nov 2020 23:33:12

US3952216

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:47:18

US3952216

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Dec 2020'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:47:18

US3952216

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:47:18

US3952216

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'VISIT3'	System	08 Dec 2020 13:47:18

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Dec 2020'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '13:36'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered '03 Dec 2020 13:36'	System	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'bpm'	System	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'breaths/min'	System	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '134'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'mmHg'	System	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 06:38:32
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'NCS' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 18:48:14
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 07:53:06
User entered '92'	Nick Bart (b) (4)	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'mmHg'	System	08 Dec 2020 13:49:48

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32

US3952216

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32

US3952216

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:02

US3952216

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:02

US3952216

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:11

US3952216

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '03 Dec 2020'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:11

US3952216

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered '13:48'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:11

US3952216

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered '03 Dec 2020 13:48'	System	08 Dec 2020 13:50:11

US3952216

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	19 Feb 2021 22:42:04
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:04

US3952216

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered '1'	System	08 Dec 2020 13:50:04

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-07T12:35:17', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7719f92f-7aa5-4f3f-a6ae-699c3627b8df' User entered 'No (N)'	System	07 Dec 2020 17:35:32

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-07T12:35:26', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7719f92f-7aa5-4f3f-a6ae-699c3627b8df' User entered 'No (N)'	System	07 Dec 2020 17:35:32

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-07T12:35:29', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '7719f92f-7aa5-4f3f-a6ae-699c3627b8df' User entered '07 Dec 2020 12:35:29'	System	07 Dec 2020 17:35:32
	System	07 Dec 2020 17:35:32

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-15T00:46:49', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '50faac2a-6a25-4197-a6e9-311c26bc0dd9' User entered 'No (N)'	System	15 Dec 2020 05:47:05
	System	15 Dec 2020 05:47:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-15T00:46:57', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '50faac2a-6a25-4197-a6e9-311c26bc0dd9' User entered 'No (N)'	System	15 Dec 2020 05:47:05
	System	15 Dec 2020 05:47:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-15T00:47:03', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '50faac2a-6a25-4197-a6e9-311c26bc0dd9' User entered '15 Dec 2020 00:47:03'	System	15 Dec 2020 05:47:05
	System	15 Dec 2020 05:47:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-20T09:55:12', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '3fd070ab-f50f-472b-9857-ea74baaa16b0' User entered 'No (N)'	System	20 Dec 2020 14:55:38
	System	20 Dec 2020 14:55:38

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-20T09:55:29', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '3fd070ab-f50f-472b-9857-ea74baaa16b0' User entered 'No (N)'	System	20 Dec 2020 14:55:38

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-20T09:55:33', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '3fd070ab-f50f-472b-9857-ea74baaa16b0' User entered '20 Dec 2020 09:55:33'	System	20 Dec 2020 14:55:38
	System	20 Dec 2020 14:55:38

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-27T11:09:39', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b905d6a6-c768-461c-aa39-c32ef9e9dedd' User entered 'No (N)'	System	27 Dec 2020 16:09:51
	System	27 Dec 2020 16:09:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-27T11:09:43', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b905d6a6-c768-461c-aa39-c32ef9e9dedd' User entered 'No (N)'	System	27 Dec 2020 16:09:51
	System	27 Dec 2020 16:09:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2020-12-27T11:09:47', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b905d6a6-c768-461c-aa39-c32ef9e9dedd' User entered '27 Dec 2020 11:09:47'	System	27 Dec 2020 16:09:51
	System	27 Dec 2020 16:09:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-04T23:58:26', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'ca15068e-b9a2-4b33-a7d1-e87f70a67aeb' User entered 'No (N)'	System	05 Jan 2021 04:58:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-04T23:58:30', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'ca15068e-b9a2-4b33-a7d1-e87f70a67aeb' User entered 'No (N)'	System	05 Jan 2021 04:58:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-04T23:58:43', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'ca15068e-b9a2-4b33-a7d1-e87f70a67aeb' User entered '04 Jan 2021 23:58:43'	System	05 Jan 2021 04:58:45
	System	05 Jan 2021 04:58:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-11T09:56:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2f11251f-63fb-4a90-a230-1f548f1b9b82'	System	11 Jan 2021 14:56:47
User entered 'No (N)'	System	11 Jan 2021 14:56:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-11T09:56:41', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2f11251f-63fb-4a90-a230-1f548f1b9b82' User entered 'No (N)'	System	11 Jan 2021 14:56:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-11T09:56:43', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '2f11251f-63fb-4a90-a230-1f548f1b9b82' User entered '11 Jan 2021 09:56:43'	System	11 Jan 2021 14:56:47
	System	11 Jan 2021 14:56:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-17T10:27:38', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '527f98c8-220a-4c63-82b9-548012a81e47'	System	17 Jan 2021 15:27:44
User entered 'No (N)'	System	17 Jan 2021 15:27:44

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-17T10:27:40', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '527f98c8-220a-4c63-82b9-548012a81e47'	System	17 Jan 2021 15:27:44
User entered 'No (N)'	System	17 Jan 2021 15:27:44

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-17T10:27:42', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '527f98c8-220a-4c63-82b9-548012a81e47' User entered '17 Jan 2021 10:27:42'	System	17 Jan 2021 15:27:44
	System	17 Jan 2021 15:27:44

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-24T18:00:20', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e7fe4b52-cf8f-4782-812e-80383297392a'	System	24 Jan 2021 23:00:45
User entered 'No (N)'	System	24 Jan 2021 23:00:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-24T18:00:22', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e7fe4b52-cf8f-4782-812e-80383297392a'	System	24 Jan 2021 23:00:45
User entered 'No (N)'	System	24 Jan 2021 23:00:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-24T18:00:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e7fe4b52-cf8f-4782-812e-80383297392a' User entered '24 Jan 2021 18:00:25'	System	24 Jan 2021 23:00:45
	System	24 Jan 2021 23:00:45

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-31T00:58:09', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '59798a2c-2f61-4a66-8a53-4056828bb107' User entered 'No (N)'	System	31 Jan 2021 05:58:18
	System	31 Jan 2021 05:58:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-31T00:58:12', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '59798a2c-2f61-4a66-8a53-4056828bb107' User entered 'No (N)'	System	31 Jan 2021 05:58:18
	System	31 Jan 2021 05:58:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-01-31T00:58:15', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '59798a2c-2f61-4a66-8a53-4056828bb107' User entered '31 Jan 2021 00:58:15'	System	31 Jan 2021 05:58:18
	System	31 Jan 2021 05:58:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-07T00:01:25', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '093052d4-bf2e-4fe1-9dc2-4caf7ecf85a0' User entered 'No (N)'	System	07 Feb 2021 05:02:07
	System	07 Feb 2021 05:02:07

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-07T00:01:28', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '093052d4-bf2e-4fe1-9dc2-4caf7ecf85a0' User entered 'No (N)'	System	07 Feb 2021 05:02:07

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-07T00:01:40', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '093052d4-bf2e-4fe1-9dc2-4caf7ecf85a0' User entered '07 Feb 2021 00:01:40'	System	07 Feb 2021 05:02:07
	System	07 Feb 2021 05:02:07

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-14T00:02:02', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b7b5e3d5-43ae-4bd8-93d8-89b5f7700f48' User entered 'No (N)'	System	14 Feb 2021 05:03:20
	System	14 Feb 2021 05:03:20

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-14T00:01:56', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b7b5e3d5-43ae-4bd8-93d8-89b5f7700f48' User entered 'No (N)'	System	14 Feb 2021 05:03:20
	System	14 Feb 2021 05:03:20

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-14T00:02:16', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b7b5e3d5-43ae-4bd8-93d8-89b5f7700f48' User entered '14 Feb 2021 00:02:16'	System	14 Feb 2021 05:03:20
	System	14 Feb 2021 05:03:20

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-21T19:56:35', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '09f23e5f-b9b8-4291-9d5d-9e4b4236aae8' User entered 'No (N)'	System	22 Feb 2021 00:56:51
	System	22 Feb 2021 00:56:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-21T19:56:39', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '09f23e5f-b9b8-4291-9d5d-9e4b4236aae8' User entered 'No (N)'	System	22 Feb 2021 00:56:51
	System	22 Feb 2021 00:56:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-21T19:56:50', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '09f23e5f-b9b8-4291-9d5d-9e4b4236aae8'	System	22 Feb 2021 00:56:51
User entered '21 Feb 2021 19:56:50'	System	22 Feb 2021 00:56:51

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-28T10:23:17-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17b51853-27f1-4bb4-abe5-66cba85c0430' User entered 'No (N)'	System	28 Feb 2021 15:23:25
	System	28 Feb 2021 15:23:25

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-28T10:23:20-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17b51853-27f1-4bb4-abe5-66cba85c0430' User entered 'No (N)'	System	28 Feb 2021 15:23:25
	System	28 Feb 2021 15:23:25

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-28T10:23:22-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '17b51853-27f1-4bb4-abe5-66cba85c0430' User entered '28 Feb 2021 15:23:22'	System	28 Feb 2021 15:23:25
	System	28 Feb 2021 15:23:25

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-09T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96c0be34-3f87-470d-8b82-1a7c1b36c524'	System	09 Mar 2021 17:02:53
User entered 'No (N)'	System	09 Mar 2021 17:02:53

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-09T12:00:41-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96c0be34-3f87-470d-8b82-1a7c1b36c524'	System	09 Mar 2021 17:02:53
User entered 'No (N)'	System	09 Mar 2021 17:02:53

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-09T12:00:44-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '96c0be34-3f87-470d-8b82-1a7c1b36c524' User entered '09 Mar 2021 12:00:44'	System	09 Mar 2021 17:02:53
	System	09 Mar 2021 17:02:53

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-14T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '001b981e-0305-45b8-9e13-9d4760a8a219'	System	14 Mar 2021 05:06:21
User entered 'No (N)'	System	14 Mar 2021 05:06:21

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-14T00:02:27-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '001b981e-0305-45b8-9e13-9d4760a8a219'	System	14 Mar 2021 05:06:21
User entered 'No (N)'	System	14 Mar 2021 05:06:21

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-14T00:02:32-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '001b981e-0305-45b8-9e13-9d4760a8a219'	System	14 Mar 2021 05:06:21
User entered '14 Mar 2021 00:02:32'	System	14 Mar 2021 05:06:21

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-21T17:10:34-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '52555963-5447-4f67-adb7-d199f0cd6250'	System	21 Mar 2021 21:10:41
User entered 'No (N)'	System	21 Mar 2021 21:10:41

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-21T17:10:36-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '52555963-5447-4f67-adb7-d199f0cd6250'	System	21 Mar 2021 21:10:41
User entered 'No (N)'	System	21 Mar 2021 21:10:41

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-21T17:10:38-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '52555963-5447-4f67-adb7-d199f0cd6250' User entered '21 Mar 2021 17:10:38'	System	21 Mar 2021 21:10:41
	System	21 Mar 2021 21:10:41

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-28T11:39:14-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '6f79709e-5a3b-4fe2-9a0f-dc3069cb0a2f'	System	28 Mar 2021 15:39:35
User entered 'No (N)'	System	28 Mar 2021 15:39:35

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-28T11:39:16-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '6f79709e-5a3b-4fe2-9a0f-dc3069cb0a2f'	System	28 Mar 2021 15:39:35
User entered 'No (N)'	System	28 Mar 2021 15:39:35

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-03-28T11:39:21-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '6f79709e-5a3b-4fe2-9a0f-dc3069cb0a2f' User entered '28 Mar 2021 11:39:21'	System	28 Mar 2021 15:39:35
	System	28 Mar 2021 15:39:35

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-04T00:02:32-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '70354dc2-1b13-458b-8167-ddab356897bf'	System	04 Apr 2021 04:03:47
User entered 'No (N)'	System	04 Apr 2021 04:03:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-04T00:02:34-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '70354dc2-1b13-458b-8167-ddab356897bf'	System	04 Apr 2021 04:03:47
User entered 'No (N)'	System	04 Apr 2021 04:03:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-04T00:02:36-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '70354dc2-1b13-458b-8167-ddab356897bf'	System	04 Apr 2021 04:03:47
User entered '04 Apr 2021 00:02:36'	System	04 Apr 2021 04:03:47

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-11T01:08:01-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'a42d49be-e80b-4bae-866b-8d35af7f5659'	System	11 Apr 2021 05:08:11
User entered 'No (N)'	System	11 Apr 2021 05:08:11

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-11T01:08:03-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'a42d49be-e80b-4bae-866b-8d35af7f5659'	System	11 Apr 2021 05:08:11
User entered 'No (N)'	System	11 Apr 2021 05:08:11

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-11T01:08:06-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'a42d49be-e80b-4bae-866b-8d35af7f5659'	System	11 Apr 2021 05:08:11
User entered '11 Apr 2021 01:08:06'	System	11 Apr 2021 05:08:11

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-18T00:25:58-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e5addefd-0de1-4b4b-9662-df8e981b9f4b'	System	18 Apr 2021 04:26:05
User entered 'No (N)'	System	18 Apr 2021 04:26:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-18T00:26:00-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e5addefd-0de1-4b4b-9662-df8e981b9f4b'	System	18 Apr 2021 04:26:05
User entered 'No (N)'	System	18 Apr 2021 04:26:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-18T00:26:03-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'e5addefd-0de1-4b4b-9662-df8e981b9f4b'	System	18 Apr 2021 04:26:05
User entered '18 Apr 2021 00:26:03'	System	18 Apr 2021 04:26:05

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-25T01:11:28-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '87dde82a-6104-4482-9db9-c6fe306bb17f' User entered 'No (N)'	System	25 Apr 2021 05:12:18
	System	25 Apr 2021 05:12:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-25T01:11:30-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '87dde82a-6104-4482-9db9-c6fe306bb17f' User entered 'No (N)'	System	25 Apr 2021 05:12:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-04-25T01:11:33-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: '87dde82a-6104-4482-9db9-c6fe306bb17f' User entered '25 Apr 2021 01:11:33'	System	25 Apr 2021 05:12:18
	System	25 Apr 2021 05:12:18

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-05-02T01:56:43-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b651c179-668a-4447-a443-ba24fd411ec3'	System	02 May 2021 05:56:50
User entered 'No (N)'	System	02 May 2021 05:56:50

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Have you been exposed to someone with 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 (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-05-02T01:56:45-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b651c179-668a-4447-a443-ba24fd411ec3'	System	02 May 2021 05:56:50
User entered 'No (N)'	System	02 May 2021 05:56:50

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-05-02T01:56:47-04:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'b651c179-668a-4447-a443-ba24fd411ec3'	System	02 May 2021 05:56:50
User entered '02 May 2021 01:56:47'	System	02 May 2021 05:56:50

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 12:11:10

US3952216

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:41:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 12:11:10
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 12:11:10

US3952216

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:41:29

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:00:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-28T10:22:56-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'd411664a-d957-4c93-948d-b0280b37a6ab' User entered 'No (N)'	System	28 Feb 2021 15:23:01
	System	28 Feb 2021 15:23:01

US3952216

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:41:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:00:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9D5343C1-926A-43B8-90FF-F72C8A330D81)', Time: '2021-02-28T10:22:59-05:00', User OID: 'PatientReportedOutcome (US3952216)', ODM File OID: 'd411664a-d957-4c93-948d-b0280b37a6ab'	System	28 Feb 2021 15:23:01
User entered '28 Feb 2021 15:22:59'	System	28 Feb 2021 15:23:01

US3952216

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:36:10

US3952216

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:36:10

US3952216

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:36:10

US3952216

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:36:10

US3952216

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:54:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Dec 2020 17:36:16

US3952216

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:37:32
User entered 'I'	System	31 Dec 2020 17:36:16

US3952216

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	03 Feb 2021 15:39:31

US3952216

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '03 Feb 2021'	(b) (4) chrishea Harvey (b) (4)	03 Feb 2021 15:39:31

US3952216

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) chrishea Harvey (b) (4)	03 Feb 2021 15:39:31

US3952216

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4)	03 Feb 2021 15:39:31
	chrishea Harvey (b) (4)	

US3952216

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) chrishea Harvey (b) (4)	03 Feb 2021 15:40:08

US3952216

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:39:43
User entered 'I'	System	03 Feb 2021 15:40:08

US3952216

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:43:23

US3952216

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:43:23

US3952216

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:43:23

US3952216

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:43:23

US3952216

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 13:43:28

US3952216

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 07:01:08
User entered 'I'	System	26 Mar 2021 13:43:28

US3952216

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:29:16

US3952216

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '02 Apr 2021'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:29:16

US3952216

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:29:16

US3952216

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:29:16

US3952216

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:29:21

US3952216

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:13:42
User entered 'I'	System	02 Apr 2021 20:29:21

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:41:29

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:31:56
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 26-Feb-2021 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC under Covid-19 Assessments. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	16 Apr 2021 04:54:27
' (Site from DM).		
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 26-Feb-2021 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC under Covid-19 Assessments. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:53:36
' answered with 'Updated' (Site from DM).		
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab: Sample dated 26-Feb-2021 is reported under Illness Visit Day 1 in PPD Central lab, however the same is missing in EDC under Covid-19 Assessments. Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.	(b) (4), (b) (6)	08 Mar 2021 06:25:40
' (Site from DM).		
User entered '12 Feb 2021'	Nick Bart (b) (4) (b) (4)	26 Feb 2021 22:06:11

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:41:29

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:31:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '20:00'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:06:11

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:41:29

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:31:56
User entered '12 Feb 2021 20:00'	System	26 Feb 2021 22:06:11

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:41:29

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:31:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Safety Call (Safety Call)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:06:11

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:41:29

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:31:56
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:06:11

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 1 (Day 1)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '06 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:07:40

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 2 (Day 2)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '07 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4) (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:01

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 3 (Day 3)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '08 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:34

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 4 (Day 4)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '09 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Not Done (Not Done)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:08:55

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 5 (Day 5)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '10 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Not Done (Not Done)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:14

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 6 (Day 6)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '11 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 7 (Day 7)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '12 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:09:49

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 8 (Day 8)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '13 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:16

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 9 (Day 9)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '14 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:33

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 10 (Day 10)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '15 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:10:56

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 11 (Day 11)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '16 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 12 (Day 12)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '17 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:11:44

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 13 (Day 13)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '18 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 14 (Day 14)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '19 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:24

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 15 (Day 15)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '20 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:12:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 16 (Day 16)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '21 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:03

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 17 (Day 17)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '22 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (17)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 18 (Day 18)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '23 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (18)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:13:45

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 19 (Day 19)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '24 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (19)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:04

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Day 20 (Day 20)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User closed query 'Per ETRTR. Please confirm if Symptoms O2 saturation, Temperature and Symptoms were assessed the day of Illness visit (26Feb21) and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:13:43
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Query 'Per ETRTR. Please confirm if Symptoms O2 saturation, Temperature and Symptoms were assessed the day of Illness visit (26Feb21) and update accordingly.' answered with 'Updated date, O2 saturation and temperature.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:39:19
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:35:10
User entered '26 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:35:10
User opened query 'Per ETRTR. Please confirm if Symptoms O2 saturation, Temperature and Symptoms were assessed the day of Illness visit (26Feb21) and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:27:26
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '25 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:35:10
User entered '97' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:35:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User entered '%'	System	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:35:10
User entered '37.4' C reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:35:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered missing code ND - Not Done.	Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Mild (Mild)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Symptom Log (20)

Generated On: 12 Aug 2021 13:41:29

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:02
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'None (None)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:14:23

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '26 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '26 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[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)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:41:29

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:07
User entered '0'	System	26 Mar 2021 13:56:31

US3952216

Folder: Covid-19 Assessment 12 Feb 2021

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:41:29

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:32:11
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	26 Mar 2021 13:56:46

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '28 Feb 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Mar 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: DAY 9 labelled sample dated 06mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:34:29
Query 'Per GCL LAB reconciliation: Saliva: DAY 9 labelled sample dated 06mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. ' answered with 'Sample was not given by subject ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 16:08:47
User opened query 'Per GCL LAB reconciliation: Saliva: DAY 9 labelled sample dated 06mar2021 is missing in PPD. Please provide the Accession # and Tracking number with the shipping date to track the sample in PPD. Thank you. ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 09:29:19
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:34
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:10:58
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 16:10:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 18:58:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:58:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	31 Mar 2021 15:09:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 15:09:45
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:09:45
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 14:29:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:29:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	16 Apr 2021 16:34:34
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 16:10:58
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 16:10:58
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:58:23
User entered '06 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:58:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:29:03
User entered '06 Mar 2021'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Signature has been broken.	(b) (4)	(b) (4), (b) (6) 09 Apr 2021 19:01:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:01:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	31 Mar 2021 15:09:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Mar 2021 15:09:45
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:09:45
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 14:27:02
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
Signature has been broken.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:01:39
User entered '11 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:01:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Per Central labs report, Day 9, Day 14 and Day 21 samples were collected. Please update.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Mimi Van Der Leden	13 Apr 2021 17:09:48 09 Apr 2021 20:19:14
Query 'Per ETRTR: Per Central labs report, Day 9, Day 14 and Day 21 samples were collected. Please update.' answered with 'Updated ' (Site from CRA). Signature has been broken.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 19:02:57 09 Apr 2021 19:02:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:02:39
User opened query 'Per ETRTR: Per Central labs report, Day 9, Day 14 and Day 21 samples were collected. Please update.' (Site from CRA). User signature succeeded.	(b) (4), (b) (6) Mimi Van Der Leden	09 Apr 2021 17:20:56 08 Apr 2021 20:43:05
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	26 Mar 2021 14:29:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 14:29:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:29:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 14:27:02
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	09 Apr 2021 20:19:14
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 19:02:39
User entered '18 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 19:02:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:41:29

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:41:29

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 14:29:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Mar 2021 14:29:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:29:03
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 14:27:02
User entered empty.	(b) (4), (b) (6)	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 14:27:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28FEB2021, 02MAR2021, 04MAR2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 07:55:39
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28FEB2021, 02MAR2021, 04MAR2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' answered with 'Sample days updated. Thank you ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:14:36
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 28FEB2021, 02MAR2021, 04MAR2021 is reported under Illness visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 04:34:33
User entered '26 Feb 2021'	Nick Bart (b) (4) (b) (4)	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:00
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:00
User entered 'SICKD1'	System	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '26 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '15:51' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 15:21:00
User entered '15:41'	Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User entered '26 Feb 2021 15:51'	System	07 Apr 2021 15:21:00
User entered '26 Feb 2021 15:41'	System	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '66.0' in	(b) (4)	26 Feb 2021 22:04:02
DataPoint set to visible.	Nick Bart (b) (4)	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '266.0' lb	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02
DataPoint set to visible.	System	26 Feb 2021 22:03:11

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '37.4' C	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '92' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:21:00
User entered '97'	Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User entered 'bpm'	System	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '16'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User entered 'breaths/min'	System	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:55:24
Query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'ncs' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:33:23
User entered '148' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 13:33:11
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP \leq 89 or \geq 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:06:20
User entered '165'	Nick Bart (b) (4) (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User entered 'mmHg'	System	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 08:50:39
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'NCS' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 17:17:01
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 14:12:23
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 16:11:01
Query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'updated.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 15:21:16
User opened query 'Per CDM: Per CCG V2.0 page 53, Diastolic Blood Pressure \geq 91 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:43:42

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Mar 2021 13:33:11
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	26 Mar 2021 13:33:11
User entered '99' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 13:33:11
User opened query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	26 Feb 2021 22:04:02
User entered '104'	Nick Bart (b) (4) (b) (4)	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10
User entered 'mmHg'	System	26 Feb 2021 22:04:02

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10

US3952216

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:10

US3952216

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:21
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:17

US3952216

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:21
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '26 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:17

US3952216

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:41:29

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:24

US3952216

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:41:29

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:42:27
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '26 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:24

US3952216

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

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:25

US3952216

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

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:25

US3952216

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

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[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 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Clinic (Clinic)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:25

US3952216

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

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'UNBLND_DECIDE'	System	08 Feb 2021 21:13:25

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:22:37

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:22:37

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:51:19
User entered 'Placebo (Placebo)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:51:24
User entered 'Placebo (Placebo)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Not Administered (NA)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	07 Apr 2021 15:51:24
User entered '1'	System	08 Feb 2021 21:13:52

US3952216

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

Form: Unblinding

Generated On: 12 Aug 2021 13:41:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '1'	System	08 Feb 2021 21:13:52

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '66.0' in	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '255.0' lb	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '41.24413'	System	08 Feb 2021 21:15:50
DataPoint set to visible.	System	08 Feb 2021 21:13:52

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '66.0' in	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '255.0' lb	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '41.24413'	System	08 Feb 2021 21:15:50
DataPoint set to visible.	System	08 Feb 2021 21:13:52

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Pre-Dose (PREDOSE)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '10:23'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '04 Feb 2021 10:23'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '37.0' C	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '80'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'bpm'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '14'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'breaths/min'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '153'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 09:09:45
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:16:39
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Feb 2021 21:15:50
User entered '119'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '66.0' in	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '255.0' lb	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:41:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '41.24413'	System	08 Feb 2021 21:15:50
DataPoint set to visible.	System	08 Feb 2021 21:13:52

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User accepted default value 'Post-Dose (POSTDOSE)'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '13:46'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '04 Feb 2021 13:46'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '98.8' F	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Oral (Oral)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '81'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'bpm'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '16'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'breaths/min'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '135'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '102'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:15:50

US3952216

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

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mmHg'	System	08 Feb 2021 21:15:50

US3952216

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:10

US3952216

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

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:10

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Feb 2021 21:18:41
User entered '04 Feb 2021' reason for change: Data Entry Error	Nick Bart (b) (4)	08 Feb 2021 21:18:41
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	08 Feb 2021 21:18:33
User entered empty.	Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Urine (URINE)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Negative (NEGATIVE)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:18:33

US3952216

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

Form: Pregnancy Test

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered empty.	System	08 Feb 2021 21:18:33

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'mRNA-1273'	System	08 Feb 2021 21:19:18
DataPoint set to visible.	System	08 Feb 2021 21:13:52

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '12:29'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '04 Feb 2021 12:29'	System	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Left Arm (LEFT ARM)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'ONCE'	System	08 Feb 2021 21:19:18

US3952216

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

Form: Exposure

Generated On: 12 Aug 2021 13:41:29

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 21:19:18

US3952216

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:20:05

US3952216

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:20:05

US3952216

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '09:42'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:20:05

US3952216

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '04 Feb 2021 09:42'	System	08 Feb 2021 21:20:05

US3952216

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:52

US3952216

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:52

US3952216

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:41:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '12:29'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:19:52

US3952216

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:41:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered '04 Feb 2021 12:29'	System	08 Feb 2021 21:19:52

US3952216

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

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:17:10

US3952216

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

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:53:57
User entered 'I'	System	08 Feb 2021 21:17:10

US3952216

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:56

US3952216

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '12 Feb 2021'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:56

US3952216

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:56

US3952216

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:41:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) Nick Bart (b) (4)	26 Feb 2021 22:04:56

US3952216

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	7 Apr 2021 15:22:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 20:29:21
User entered 'Yes (Y)'	Nick Bart (b) (4)	26 Feb 2021 22:05:01

US3952216

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User entered '1'	System	07 Apr 2021 15:22:39
User entered empty.	System	30 Mar 2021 20:29:21
User entered '1'	System	26 Feb 2021 22:05:01

US3952216

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:41:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 17:30:39
User entered '1'	System	07 Apr 2021 15:22:39
User entered empty.	System	30 Mar 2021 20:29:21
User entered '1'	System	26 Feb 2021 22:05:01
DataPoint set to visible.	System	26 Feb 2021 22:05:01

US3952216

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:03:56

US3952216

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	09 Apr 2021 11:11:53
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
Query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' answered with 'per eCRF subject underwent D57 visit, received one dose in oct 2020 second during OL D1 in Feb2021' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:05:30
User opened query 'OL-D29 Visit Date is < 25 days or > 42 days after the Participant Decision visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Apr 2021 16:03:56
User entered '05 Apr 2021'	(b) (4), (b) (6)	07 Apr 2021 16:03:56

US3952216

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:03:56

US3952216

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:41:29

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	07 Apr 2021 16:03:56

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '09:50'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:50'	System	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '37.4' C	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered empty.	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '80'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '17'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '133'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '98'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	07 Apr 2021 16:06:43

US3952216

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:07:00

US3952216

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:41:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6)	07 Apr 2021 16:07:00

US3952216

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:07:28

US3952216

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '05 Apr 2021'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:07:28

US3952216

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '10:42'	(b) (4) (b) (4), (b) (6) [REDACTED]	07 Apr 2021 16:07:28

US3952216

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:41:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 10:42'	System	07 Apr 2021 16:07:28

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:20

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:20

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'I'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:20

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:20

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:36
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:20

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '10:44'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User entered '04 Feb 2021 10:44'	System	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '94'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User entered 'bpm'	System	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User entered 'breaths/min'	System	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User closed query 'Per CDM: Systolic Blood Pressure is reported as 170 mmHg. However Per CCG, Systolic Blood Pressure \geq 141 mmHg is to be considered out of range Please consider to review and confirm if CS or NCS. if CS, please consider to update the Adverse Events eCRF' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:32:02
Query 'Per CDM: Systolic Blood Pressure is reported as 170 mmHg. However Per CCG, Systolic Blood Pressure \geq 141 mmHg is to be considered out of range Please consider to review and confirm if CS or NCS. if CS, please consider to update the Adverse Events eCRF' answered with 'ncs' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 13:29:57
User entered '138' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 13:29:39
User opened query 'Per CDM: Systolic Blood Pressure is reported as 170 mmHg. However Per CCG, Systolic Blood Pressure \geq 141 mmHg is to be considered out of range Please consider to review and confirm if CS or NCS. if CS, please consider to update the Adverse Events eCRF' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 09:52:02
User entered '170'	Nick Bart (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User entered 'mmHg'	System	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 11:32:04
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 13:30:03
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		26 Mar 2021 13:29:39
User entered '101' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 13:29:39
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 09:10:07
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:24:44
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Feb 2021 21:23:47
User entered '107'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:40
User entered 'mmHg'	System	08 Feb 2021 21:23:47

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:23:40

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:23:40

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:46
Data entry locked.	(b) (4), (b) (6)	01 May 2021 01:23:45
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:22

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Physical Exam](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:46
Data entry locked.	(b) (4), (b) (6)	01 May 2021 01:23:45
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:22

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:46
Data entry locked.	(b) (4), (b) (6)	01 May 2021 01:23:45
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'l'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:22

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:46
Data entry locked.	(b) (4), (b) (6)	01 May 2021 01:23:45
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:22

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Unscheduled Visit Assessment

Generated On: 12 Aug 2021 13:41:29

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:46
Data entry locked.	(b) (4), (b) (6)	01 May 2021 01:23:45
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '0'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:22

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '04 Feb 2021'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '11:47'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User entered '04 Feb 2021 11:47'	System	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered empty.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '91'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User entered 'bpm'	System	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered missing code ND - Not Done.	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User entered 'breaths/min'	System	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User entered '138'	(b) (4) Nick Bart (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User entered 'mmHg'	System	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:19
User closed query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 09:10:21
Query 'Diastolic Blood Pressure reported is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:25:55
User opened query 'Diastolic Blood Pressure reported System is out of range > 100 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		08 Feb 2021 21:25:48
User entered '101'	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 01:23:50
User entered 'mmHg'	System	08 Feb 2021 21:25:48

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:23:50

US3952216

Folder: Unscheduled 04 Feb 2021

Form: Vital Signs

Generated On: 12 Aug 2021 13:41:29

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	01 May 2021 01:23:50

US3952216

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:41:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:46:35
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 19:15:12
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 14:58:06

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:31
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:09:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:09:37
Data point term sent to Coder	System	27 Oct 2020 15:08:51
User entered 'hypertension'	Nick Bart (b) (4) (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Nick Bart (b) (4)	03 Feb 2021 20:51:49
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '16 Oct 2020'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)' reason for change: New Information	(b) (4) Nick Bart (b) (4)	08 Dec 2020 13:50:57
User entered 'Yes (Y)'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '06 Nov 2020' reason for change: New Information	(b) (4)	03 Feb 2021 20:51:33
User entered '03 Dec 2020' reason for change: New Information	Nick Bart (b) (4)	08 Dec 2020 13:50:57
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	08 Dec 2020 13:51:17
User entered empty; reason for change New Information	Nick Bart (b) (4)	08 Dec 2020 13:51:17
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	(b) (4)	08 Dec 2020 13:50:57
User entered '13:36' reason for change: New Information	System	08 Dec 2020 13:50:57
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Dec 2020 13:51:17
User entered '03 Dec 2020 13:36'	System	08 Dec 2020 13:50:57
User entered empty.	System	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Severity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4)	03 Feb 2021 20:51:33
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Nick Bart (b) (4)	27 Oct 2020 15:08:02
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Death](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	(b) (4) Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'None (NONE)' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Feb 2021 20:51:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 18:47:10
User entered 'None (NONE)'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[None](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4)	
	Nick Bart (b) (4)	27 Oct 2020 15:08:02
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'l'	(b) (4)	
	Nick Bart (b) (4)	27 Oct 2020 15:08:02
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	08 Dec 2020 13:50:57
Data Entry Error	Nick Bart (b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4)	
	Nick Bart (b) (4)	27 Oct 2020 15:08:02
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4)	
	Nick Bart (b) (4)	27 Oct 2020 15:08:02
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:41:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Feb 2021 20:51:49
User entered '0'	System	27 Oct 2020 15:08:02

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 20:53:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Feb 2021 20:53:36
Data point term sent to Coder	System	03 Feb 2021 20:53:16
User entered 'hypertension'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '06 Nov 2020'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	03 Feb 2021 20:53:08
User entered empty; reason for change Data Entry Error	Nick Bart (b) (4)	03 Feb 2021 20:53:08
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	03 Feb 2021 20:52:59
User entered '09:31'	System	03 Feb 2021 20:52:59
	Nick Bart (b) (4)	03 Feb 2021 20:52:59
	(b) (4)	

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
User entered empty.	System	03 Feb 2021 20:53:08
User entered '06 Nov 2020 09:31'	System	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User closed query 'Per DM CLR: RQ: Per previous response it was reported as "gone down in severity". Please con firm whether the AE is completely resolved or severity is decreased. Please review and update ongoing section as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Mar 2021 12:10:19
Query 'Per DM CLR: RQ: Per previous response it was reported as "gone down in severity". Please con firm whether the AE is completely resolved or severity is decreased. Please review and update ongoing section as appropriate. Thank you.' answered with 'Resolved ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:15:43
User opened query 'Per DM CLR: RQ: Per previous response it was reported as "gone down in severity". Please con firm whether the AE is completely resolved or severity is decreased. Please review and update ongoing section as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:03:36
User closed query 'Per DM CLR: Please review if this AE is really resolved as a chronic condition is not usually listed as resolved. Please review and update if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 09:03:36
Query 'Per DM CLR: Please review if this AE is really resolved as a chronic condition is not usually listed as resolved. Please review and update if applicable. Otherwise, clarify.' answered with 'This subject experienced hypertension that has since gone down in severity' (Site from DM).	Nick Bart (b) (4) (b) (4)	08 Feb 2021 21:27:46

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this AE is really resolved as a chronic condition is not usually listed as resolved. Please review and update if applicable. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	07 Feb 2021 20:15:21
User entered '02 Dec 2020'	Nick Bart (b) (4) (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
User entered empty.	System	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	Nick Bart	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 12:10:49
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' answered with 'Could you provide clarity to this query please per source the subject was withdrawn but did opt to receive OL injection ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:19:45
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 13:35:22
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 20:53:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Feb 2021 20:53:13
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Nick Bart (b) (4)	03 Feb 2021 20:53:13
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Feb 2021 20:52:59
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'I'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Nick Bart (b) (4) (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	Nick Bart (b) (4)	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
User entered '0'	System	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07
User entered '0'	System	03 Feb 2021 20:52:59

US3952216

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:41:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:07

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:20:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 20:20:43
Data point term sent to Coder	System	02 Apr 2021 20:20:17
User entered 'Cough'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
User signature succeeded.	Mimi Van Der Leden	15 Apr 2021 20:22:10
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User closed query 'Per ETRTR: Please confirm if event is a confirmed diagnosis of Symptomatic Covid-19 if not, please update.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:04:25
Query 'Per ETRTR: Please confirm if event is a confirmed diagnosis of Symptomatic Covid-19 if not, please update.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 18:29:12
Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 18:28:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 18:28:54
User opened query 'Per ETRTR: Please confirm if event is a confirmed diagnosis of Symptomatic Covid-19 if not, please update.' (Site from CRA).	(b) (4), (b) (6)	09 Apr 2021 17:24:00
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '06 Feb 2021'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
User entered empty.	System	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '25 Feb 2021'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
User entered empty.	System	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'No (N)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered '0'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:39
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:42
User signature succeeded.	Mimi Van Der Leden	07 Apr 2021 21:24:05
User entered empty.	(b) (4), (b) (6)	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
User entered '0'	System	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:31:12
User entered '0'	System	02 Apr 2021 20:19:45

US3952216

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 12 Aug 2021 13:41:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED] [REDACTED]	28 Apr 2021 22:31:12

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:41:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 14:46:35
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'Yes (Y)'	(b) (4) Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:01:33

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 21:04:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:04:25
Data point term sent to Coder	System	13 Oct 2020 21:03:04
User entered 'adderrall er'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:02:31

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:11:47
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:41:43
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 10:27:42
User entered 'Attention deficit hyperactivity disorder'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:02:31

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '30'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'un UNK 1996'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 21:02:31
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:02:31

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:02:31

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Oct 2020 21:02:31

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: HORMONAL CONTRACEPTIVES FOR SYSTEMIC USE, ATC: PROGESTOGENS, PRODUCT: ETONOGESTREL, PRODUCTSYNONYM: NEXPLANON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 21:05:29
Data point term sent to Coder	System	13 Oct 2020 21:04:07
User entered 'nexplanon'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:11:56
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:43:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:43:36
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 17:01:40
User entered 'No (N)'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'contraception'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '68'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'other (OTHER)'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'every five years'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 09:11:59
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'route is correct as entered' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:43:31
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 17:02:02
User entered 'Subcutaneous (SUBCUTANEOUS)'	Nick Bart (b) (4) (b) (4)	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'un UNK 2015'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'Yes (Y)'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	13 Oct 2020 21:03:39
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 21:03:39

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
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: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Oct 2020 15:19:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Oct 2020 15:19:43
Data point term sent to Coder	System	27 Oct 2020 15:18:03
User entered 'lisinopril'	Nick Bart (b) (4) (b) (4)	27 Oct 2020 15:17:56

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'hypertension'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '20'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'mg (mg)'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'once daily (QD)'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'Oral (ORAL)'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

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

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '17 Oct 2020'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered '0'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per CDM: Please check corresponding AE has been ended however medication is marked as ongoing. Kindly reconcile the data and updated as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 06:44:56
Query 'Per CDM: Please check corresponding AE has been ended however medication is marked as ongoing. Kindly reconcile the data and updated as appropriate. Thank you.' answered with 'Subject is still taking medication' (Site from DM).	Nick Bart (b) (4) (b) (4)	04 Jan 2021 18:44:14
User opened query 'Per CDM: Please check corresponding AE has been ended however medication is marked as ongoing. Kindly reconcile the data and updated as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 12:15:44
User entered 'Yes (Y)'	Nick Bart (b) (4) (b) (4)	27 Oct 2020 15:17:56

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered empty.	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
	(b) (4)	
User entered 'No (N)'	Nick Bart (b) (4)	27 Oct 2020 15:17:56
	(b) (4)	

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:17:56

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Oct 2020 15:17:56

US3952216

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:41:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Oct 2020 15:17:56

US3952216

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:41:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) [REDACTED]	26 Mar 2021 13:48:07

US3952216

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:41:29

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:10
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:05
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User entered '06 Nov 2020'	Nick Bart (b) (4)	11 Nov 2020 15:04:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:41:29

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:10
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:07
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:38:21
Query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 18:45:11
User opened query 'Per CDM: Per this form the AE is recorded as reason for dose discontinuation; however action taken with investigational product is not recorded as IP withdrawn. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 18:34:26
User entered 'AE (specify) (ADVERSE EVENT)'	Nick Bart (b) (4)	11 Nov 2020 15:04:57

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:41:29

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 15:53:10
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:06:02
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:05:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:04:58
User signature succeeded.	Mimi Van Der Leden	08 Apr 2021 20:43:05
User closed query 'PER CDM: RE-QUERY: In other specify it was recorded as #1. However, in AE page Action taken with investigational product was recorded as IP WITHDRAWN for AE #2. Please review/reconcile or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 15:06:20
Query 'PER CDM: RE-QUERY: In other specify it was recorded as #1. However, in AE page Action taken with investigational product was recorded as IP WITHDRAWN for AE #2. Please review/reconcile or clarify. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:07:34
User entered '#2' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 15:07:10
User opened query 'PER CDM: RE-QUERY: In other specify it was recorded as #1. However, in AE page Action taken with investigational product was recorded as IP WITHDRAWN for AE #2. Please review/reconcile or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:34:57

US3952216

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:41:29

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
User closed query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:33:01
Query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 14:13:01
User entered ' #1' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 14:12:46
User opened query 'Per CDM: Per sponsor review, if reason for dosing discontinuation is AE/SAE, then AE specify field must include '#' symbol and 'AE logline number'. Please consider updating AE specify field to include only the '#' symbol and 'AE logline number' (i.e. #1 for row 1). ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:47:06
Query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 14:45:38
User opened query 'Per CDM: Per sponsor review, please consider updating specify field to include only AE, number sign, and number. (i.e. AE #1). Thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:29:23
User closed query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 09:38:26
Query 'Per CDM: Please record AE record number instead of details ' answered with 'updated' (Site from DM).	Nick Bart (b) (4)	04 Jan 2021 18:44:59
User entered '1' reason for change: Data Entry Error	Nick Bart (b) (4)	04 Jan 2021 18:44:55
User opened query 'Per CDM: Please record AE record number instead of details ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 17:02:08
User entered 'hypertension'	Nick Bart (b) (4)	11 Nov 2020 15:04:57