

US3322388 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:17:09

All time stamps listed in this document are displayed in GMT

US3322388

Form: Participant Creation

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

Participant ID

US3322388

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

US3322388

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Feb 2021 04:09:31

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Feb 2021 04:09:32

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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) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	OBESITY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	CODEINE (HIVES)
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	NAPROXEN (HIVES)
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	21 SEP 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	21 SEP 1990
Stop date completely unknown	False
Start Month and Year (derived)	SEP 1990
Start Year (derived)	1990
Stop Month and Year (derived)	SEP 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	11 JUL 1984
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)	11 JUL 1984
Stop date completely unknown	False
Start Month and Year (derived)	JUL 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JUL 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	CESAREAN SECTION
Start date (dd MMM yyyy)	24 MAR 1982
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)	24 MAR 1982
Stop date completely unknown	False
Start Month and Year (derived)	MAR 1982
Start Year (derived)	1982
Stop Month and Year (derived)	MAR 1982
Stop Year (derived)	1982

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	TOTAL HYSTERECTOMY DUE TO FIBROIDS
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	VENTRAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	VENTRAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Condition	UPPER AND LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	15:43 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 15:43
Height (xxx.x)	65.5 in
Weight (xxx.x)	176 lb
BMI (xxx.x)	28.90280 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Feb 2021 04:09:31

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Date of assessment (dd MMM yyyy) 21 SEP 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) UN UNK 2012

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: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Feb 2021 04:09:32

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

What was the date of randomization? (dd MMM yyyy) 28 SEP 2020

What was the participant's randomization number? 115576

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) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Height	65.5 in
Weight	176 lb

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Height	65.5 in
Weight	176 lb
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)	28 SEP 2020
Time of assessment (00:00-23:59)	11:10 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 11:10
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	153 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Height	65.5 in
Weight	176 lb
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)	28 SEP 2020
Time of assessment (00:00-23:59)	13:42 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:42
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 13:04 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 13:04

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) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

12:53 (24 HR)

Collection date and time (derived)

28 SEP 2020 12:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:51	28 SEP 2020 12:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:32

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 13:44

PC Open Date & Time

28 SEP 2020 13:24

PC Close Date & Time

28 SEP 2020 15:54

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	28 SEP 2020 19:07
PC Open Date & Time	28 SEP 2020 16:49
PC Close Date & Time	29 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 23:16

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 13:08

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 14:12

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:42

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 13:55

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

04 OCT 2020 12:02

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 13:48

PC Open Date & Time

28 SEP 2020 13:24

PC Close Date & Time

28 SEP 2020 15:54

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

28 SEP 2020 19:08

PC Open Date & Time

28 SEP 2020 16:49

PC Close Date & Time

29 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 23:17

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

30 SEP 2020 13:09

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

01 OCT 2020 14:13

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

02 OCT 2020 12:43

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

03 OCT 2020 13:55

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

04 OCT 2020 12:03

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 13:50
PC Open Date & Time	28 SEP 2020 13:24
PC Close Date & Time	28 SEP 2020 15:54

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 19:09
PC Open Date & Time	28 SEP 2020 16:49
PC Close Date & Time	29 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 23:18
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 3526

EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 13:09
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 14:15
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

63 of 3526

EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:43
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 3526

EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 13:57
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 3526

EAB) (1725)

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	VISIT2

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

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)	26 OCT 2020
Time of assessment (00:00-23:59)	11:35 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 11:35
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

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)	26 OCT 2020
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 13:46
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

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) 26 OCT 2020

What was the treatment time? (00:00-23:59) 13:01 (24 HR)

Treatment Date and Time (derived) 26 OCT 2020 13:01

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

US3322388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

12:55 (24 HR)

Collection date and time (derived)

26 OCT 2020 12:55

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)			26 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	26 OCT 2020 12:50
Nasopharyngeal Swab 2	No		

US3322388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 13:50

PC Open Date & Time

26 OCT 2020 13:21

PC Close Date & Time

26 OCT 2020 15:51

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	26 OCT 2020 18:12
PC Open Date & Time	26 OCT 2020 16:46
PC Close Date & Time	27 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 OCT 2020 17:21

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 05:43

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 OCT 2020 14:32

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 18:29

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 OCT 2020 13:53

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 NOV 2020 14:20

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

26 OCT 2020 13:50

PC Open Date & Time

26 OCT 2020 13:21

PC Close Date & Time

26 OCT 2020 15:51

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

26 OCT 2020 18:13

PC Open Date & Time

26 OCT 2020 16:46

PC Close Date & Time

27 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 OCT 2020 17:22

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

29 OCT 2020 05:44

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

29 OCT 2020 14:32

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 OCT 2020 18:29

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 OCT 2020 13:54

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 NOV 2020 14:21

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

No ☒

Yes ☐

PC Time stamp	26 OCT 2020 13:51
PC Open Date & Time	26 OCT 2020 13:21
PC Close Date & Time	26 OCT 2020 15:51

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

No ☒

Yes ☐

PC Time stamp	26 OCT 2020 18:14
PC Open Date & Time	26 OCT 2020 16:46
PC Close Date & Time	27 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

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 ☒

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 17:22
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

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)

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 05:44
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 14:33
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 18:31
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 13:56
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

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 ☒

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 14:22
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3322388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 DEC 2020
Time of assessment (00:00-23:59)	11:02 (24 HR)
Vital Signs Date and Time (derived)	7 DEC 2020 11:02
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 DEC 2020

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

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 DEC 2020

Collection time (00:00-23:59)

11:57 (24 HR)

Collection date and time (derived)

07 DEC 2020 11:57

US3322388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:35

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	26 NOV 2020 18:18:10
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	04 DEC 2020 07:44:29
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	09 DEC 2020 11:55:11
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	17 DEC 2020 12:21:40
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 13:13:02
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	30 DEC 2020 17:39:36
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

07 JAN 2021 14:43:32

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	14 JAN 2021 17:30:30
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 14:10:07

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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	27 JAN 2021 14:52:03
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 08:38:08

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	10 FEB 2021 21:17:01
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 FEB 2021 18:47:39
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

24 FEB 2021 08:28:55

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 <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	03 MAR 2021 18:47:17
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 14:31:55
Patient Cloud Open Date & Time	10 MAR 2021 00:01
Patient Cloud Close Date & Time	14 MAR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 01:41:13

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

24 MAR 2021 17:44:29

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 APR 2021 16:09:22
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

09 APR 2021 09:21:59

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 APR 2021 18:34:18
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 11:12:40

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 15:50:38

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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="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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	24 OCT 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐
Yes ☐

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	27 FEB 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JUN 2022 00:01
Patient Cloud Close Date & Time	26 JUN 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
Patient Cloud Close Date & Time	28 AUG 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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="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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

Date and time of submission	
Patient Cloud Open Date & Time	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

13 NOV 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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°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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

20 NOV 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

27 NOV 2022 23:59

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

[Patient Cloud Close Date & Time](#)

04 DEC 2022 23:59

US3322388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:17:09

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	01 MAR 2021 17:41:25

US3322388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

Visit date (dd MMM yyyy)	12 APR 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	VISIT4
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US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	11:29 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 11:29
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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.

US3322388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 APR 2021

Collection time (00:00-23:59)

11:44 (24 HR)

Collection date and time (derived)

12 APR 2021 11:44

US3322388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Date of Contact	21 DEC 2020
Time of Contact	22:09
Date and Time of Contact (derived)	21 DEC 2020 22:09
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Moderate	<input checked="" 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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US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Moderate	<input checked="" 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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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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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Form: Symptom Log (3)

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

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	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:37:41

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Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:37:41

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

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Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (6)

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Generated On: 11 Aug 2021 22:17:09

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	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 type="radio"/>
	Moderate	<input checked="" 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 (7)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

Date	21 DEC 2020
------	-------------

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

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

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

Temperature	100 F
-------------	-------

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

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

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

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

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Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	22 DEC 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	102 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 21 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	23 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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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Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	98 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	25 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 (12)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 16:37:41

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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)

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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	26 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	100.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input checked="" type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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

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Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 DEC 2020	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 16:37:41

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Symptom Day

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 16:37:41

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Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input 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) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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	29 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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	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 21 Dec 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 (17)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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 21 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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	31 DEC 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" 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 21 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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	1 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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 21 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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	2 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
PRODUCTION RELEASE (v12.003		409 of 3526
EAB) (1725)		

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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"/>

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 21 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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	3 JAN 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

	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"/>

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Date of Visit	21 DEC 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	21 DEC 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:09:29

Generated On: 11 Aug 2021 22:17:09

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

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

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

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

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

If Yes, provide:

Start Date 22 DEC 2020

End Date 22 DEC 2020

Oxygen Saturation 93 %

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

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

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

Start Date _____

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:09:29

Generated On: 11 Aug 2021 22:17:09

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

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Feb 2021 04:09:29

Generated On: 11 Aug 2021 22:17:09

Hepatic Dysfunction? Yes ☐ No ☒

Start Date

Neurologic Dysfunction? Yes ☐ No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐ No ☒

Date of Assessment

Radiographical Evidence Yes ☐ No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐ No ☒

Start Date

End Date

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Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Date of Contact	30 NOV 2020
Time of Contact	11:25
Date and Time of Contact (derived)	30 NOV 2020 11:25
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input 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 30 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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 30 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (5)

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:09:30

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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 30 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input 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 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	28 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:09:30

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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 30 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 26 Feb 2021 04:09:30

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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 30 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

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Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	97 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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 30 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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	1 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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	2 DEC 2020
------	------------

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

O2 Saturation	100 %
---------------	-------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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"/>

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

	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"/>

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Feb 2021 04:09:30

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Date of Visit	30 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	30 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input type="radio"/> Nasal Swab <input checked="" 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

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	02 DEC 2020
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 DEC 2020
Day 5	Yes	25 DEC 2020
Day 7	Yes	28 DEC 2020
Day 9	Yes	29 DEC 2020
Day 14	Yes	03 JAN 2021
Day 21	Yes	11 JAN 2021
Day 28	Yes	18 JAN 2021

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 NOV 2020
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	30 NOV 2020 12:15
Height (xxx.x)	65 in
Weight (xxx.x)	175.5 lb
Temperature (xxx.x)	97 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 NOV 2020

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

US3322388

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 NOV 2020

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

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

Visit date (dd MMM yyyy)	21 DEC 2020
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 DEC 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 15:00
Height (xxx.x)	65.5 in
Weight (xxx.x)	171 lb
Temperature (xxx.x)	100 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 DEC 2020

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

US3322388

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Feb 2021 04:09:31

Generated On: 11 Aug 2021 22:17:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 DEC 2020

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 11:30
Height (xxx.x)	65.5 in
Weight (xxx.x)	176 lb
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3322388

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

18 JAN 2021

US3322388

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

Form: Visit Date

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

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

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

Folder OID	UNBLND_DECIDE
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US3322388

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Date of updated informed consent (<i>dd MMM yyyy</i>)	04 MAR 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	24 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3322388

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

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

US3322388

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	11:19 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 11:19
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	04 MAR 2021
Time of assessment (00:00-23:59)	13:46 (24 HR)
Vital Signs Date and Time (derived)	04 MAR 2021 13:46
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

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

Form: Physical Examination

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 MAR 2021

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

US3322388

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

Form: Exposure

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

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 MAR 2021

What was the treatment time? (00:00-23:59) 13:06 (24 HR)

Treatment Date and Time (derived) 04 MAR 2021 13:06

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

US3322388

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 MAR 2021

Collection time (00:00-23:59)

12:07 (24 HR)

Collection date and time (derived)

04 MAR 2021 12:07

US3322388

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 MAR 2021

Collection time (00:00 - 23:59)

12:02

Collection Date and Time (derived)

04 MAR 2021 12:02

US3322388

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

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

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

Visit date (dd MMM yyyy)	29 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

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)	29 MAR 2021
Time of assessment (00:00-23:59)	11:15 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 11:15
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

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)	29 MAR 2021
Time of assessment (00:00-23:59)	12:29 (24 HR)
Vital Signs Date and Time (derived)	29 MAR 2021 12:29
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3322388

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 MAR 2021

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

US3322388

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

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) 29 MAR 2021

What was the treatment time? (00:00-23:59) 11:53 (24 HR)

Treatment Date and Time (derived) 29 MAR 2021 11:53

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

US3322388

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 01 Apr 2021 00:01:16

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

06 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3322388

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 23 Apr 2021 16:37:41

Generated On: 11 Aug 2021 22:17:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3322388

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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 _____

US3322388

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

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)	

US3322388

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

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.

US3322388

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

US3322388

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Feb 2021 04:09:28

Generated On: 11 Aug 2021 22:17:09

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

AEID

Adverse event

DIARRHEA

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)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

01 OCT 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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

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 type="radio"/> Related <input checked="" 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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

AEID

Adverse event

HUMAN
RHINOVIRUS/ENTEROVIRUS
SINUSITIS

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)

20 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)

03 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 ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

AEID

Adverse event

GENERALIZED MYALGIA

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)

23 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)

25 NOV 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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

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	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)	

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

AEID	USA-US060-2021-MRNA-1273-P30 1000005
Adverse event	SYMPTOMATIC COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	14 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	02 JAN 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"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 26 Feb 2021 04:09:27

Generated On: 11 Aug 2021 22:17:09

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

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

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

Yes ☒

No ☐

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

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication VISTARIL (HYDROXYZINE)

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

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Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication UPPER AND LOWER BACK PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication VITAMIN D 3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes <input checked="" type="radio"/>	No <input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication VITAMIN C

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication OBESITY

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication PROBIOTICS

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 12

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication ESTROGENS-METHYLTESTOSTERONE

Prophylaxis Yes ☐
No ☒

Indication POSTMENOPAUSE

Dose per administration 0.625/1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (10)

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Name of Medication MULTIVITAMIN WITH NO IRON

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration ONE

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

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Name of Medication CALCIUM -MAG- ZINC

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration ONE PER DAY

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Mar 2021 22:11:30

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

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication AMOXICILLIN / CLAVULANIC
ACID (AUGMENTIN)

Prophylaxis Yes ☐
No ☒

Indication HUMAN
RHINOVIRUS/ENTEROVIRUS
SINUSITIS

Dose per administration 875/125

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Transdermal	<input type="checkbox"/>
	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication GUAIFENESIN (MUCINEX)

Prophylaxis Yes ☐
No ☒

Indication HUMAN
RHINOVIRUS/ENTEROVIRUS
SINUSITIS

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication PREVENTATIVE HEALTHCARE

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		09 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication LOPERAMIDE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	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)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Name of Medication BOTOX

Prophylaxis Yes ☐
No ☒

Indication COSMETIC

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 24 Mar 2021 22:11:30

Generated On: 11 Aug 2021 22:17:09

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 NOV 2020	COVID-19 NASAL SWAB (NEGATIVE RESULT)	Diagnostic	
24 NOV 2020	COVID-19 NASAL SWAB (NEGATIVE RESULT)	Diagnostic	

US3322388

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:17:09

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3322388

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:17:09

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 ☐

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/JAN/2021 16:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	06/JAN/2021 16:25
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	11/JAN/2021 11:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/JAN/2021 16:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Mar 2021 22:11:31

Generated On: 11 Aug 2021 22:17:09

SAEID	USA-US060-2021-MRNA-1273-P301000005
Serious	Yes <input type="radio"/> No <input checked="" type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	VERONICA
Investigator's Last Name	FRAGOSO
Site Address: Street	6550 MAPLERIDGE STREET
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77081
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 07:46
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3322388 (Prod: DM Clinical Research - Texas Center For Drug Development - ERN - PPDS)

US3322388

Form: Participant Creation

Generated On: 11 Aug 2021 22:17:09

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'US3322388'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 20:40:30

US3322388

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:27:54

US3322388

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	(b) (4)	
	System	28 Sep 2020 21:27:39
User opened query 'Visit date is prior to the Date of informed consent. Please review and provide any needed correction.' (Site from System).	System	28 Sep 2020 18:21:35
User entered '21 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 20:40:31

US3322388

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:27:54

US3322388

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'SCRN'	System	28 Sep 2020 21:27:54

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 20:40:32

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Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '60'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'YEARS'	System	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '60'	System	28 Sep 2020 18:21:35

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Female (F)'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'I'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:17:09

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	24 Sep 2020 21:20:57

US3322388

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Blessing Felix-Okoroji	28 Sep 2020 21:27:39
User entered '28 Sep 2020'	(b) (4)	
	Frances Saubon (b) (4)	28 Sep 2020 18:21:35
	(b) (4)	

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Sep 2020'	System	28 Sep 2020 18:21:35

US3322388

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2020'	System	28 Sep 2020 18:21:35

US3322388

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Amendment 3 (3)'	Frances Saubon (b) (4)	28 Sep 2020 18:21:35

US3322388

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 16-17. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Sep 2020 21:47:32
User entered 'Yes (Y)'	Frances Saubon (b) (4)	28 Sep 2020 18:21:35
Query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 16-17. ' answered with 'Visit incomplete, will complete data once source is complete.' (Site from DM).	(b) (4) Frances Saubon (b) (4)	27 Sep 2020 03:49:14
User opened query 'Per CDM: Please indicate if subject was enrolled in the study and complete the appropriate eCRF forms as indicated in the CCGs pages 16-17. ' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 15:47:35

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	28 Sep 2020 18:21:35

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	28 Sep 2020 18:21:35

US3322388

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	28 Sep 2020 18:21:35

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	21 Sep 2020 20:40:31

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Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:17:09

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'I'	System	28 Sep 2020 18:21:40

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:17:09

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Frances Saubon (b) (4)	28 Sep 2020 18:21:40

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Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:17:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:09

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:16:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 14:16:56
User closed query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Oct 2020 14:41:48
' (Site from DM).		
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Frances Saubon (b) (4)	27 Oct 2020 16:08:51
' answered with 'updated' (Site from DM).		
Data point term sent to Coder	System	27 Oct 2020 16:08:42
Coding entries removed.	Frances Saubon (b) (4)	27 Oct 2020 16:08:42
User entered 'Osteoarthritis, bilateral hands and hips' reason for change: Per Query Resolution	Frances Saubon (b) (4)	27 Oct 2020 16:08:42
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	27 Oct 2020 15:32:20
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:29:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:29:51

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	28 Sep 2020 21:29:09
User entered 'Arthritis'	Blessing Felix-Okoroji	28 Sep 2020 21:28:39
	(b) (4)	

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2015'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:39

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:39

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Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2015'	System	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2015'	System	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:28:39

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:15
Data point term sent to Coder	System	28 Sep 2020 21:30:10
User entered 'Insomnia'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2010'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

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Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2010'	System	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2010'	System	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:29:31

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:13
Data point term sent to Coder	System	28 Sep 2020 21:30:10
User entered 'anxiety'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2015'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2015'	System	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2015'	System	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:29:50

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:31:16
Data point term sent to Coder	System	28 Sep 2020 21:30:12
User entered 'acid reflux'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN Jan 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2020'	System	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2020'	System	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:11

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
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.	Coder Import (b) (4)	28 Sep 2020 21:32:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:32:02
Data point term sent to Coder	System	28 Sep 2020 21:31:14
User entered 'Obesity'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

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Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2012'	System	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2012'	System	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:32

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 08:56:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 08:56:54
Data point term sent to Coder	System	28 Sep 2020 21:31:15
User entered 'codeine (hives)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 1990'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 1990'	System	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1990'	System	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:30:55

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Urticaria drug-induced - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:37:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 05:37:51
Data point term sent to Coder	System	28 Sep 2020 21:31:15
User entered 'naproxen (Hives)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2017'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2017'	System	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2017'	System	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	28 Sep 2020 21:31:15

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:01
Data point term sent to Coder	System	09 Dec 2020 14:17:22
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 14:16:31
User entered 'Cesarean SECTION' reason for change: Data Entry Error	Frances Saubon (b) (4)	09 Dec 2020 14:16:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:33:46
Data point term sent to Coder	System	28 Sep 2020 21:32:16
User entered 'C-section'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Sep 1990'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Sep 1990'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Sep 1990'	System	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1990'	System	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Sep 1990'	System	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (8)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1990'	System	28 Sep 2020 21:31:51

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:00
Data point term sent to Coder	System	09 Dec 2020 14:17:23
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 14:16:47
User entered 'Cesarean SECTION' reason for change: Data Entry Error	Frances Saubon (b) (4)	09 Dec 2020 14:16:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:33:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:33:46
Data point term sent to Coder	System	28 Sep 2020 21:32:17
User entered 'C-section'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '11 Jul 1984' reason for change: Data Entry Error	System	28 Sep 2020 21:32:43
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Blessing Felix-Okoroji	28 Sep 2020 21:32:43
User entered '11 Jul 198' (non-conformant).	(b) (4)	
	System	28 Sep 2020 21:32:12
	Blessing Felix-Okoroji	28 Sep 2020 21:32:12
	(b) (4)	

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 21:32:43
User entered 'No (N)' reason for change: Data Entry Error	Blessing Felix-Okoroji	28 Sep 2020 21:32:43
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	28 Sep 2020 21:32:12
	Blessing Felix-Okoroji	28 Sep 2020 21:32:12
	(b) (4)	

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '11 Jul 1984' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:32:43
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jul 1984'	System	28 Sep 2020 21:32:43
User entered empty.	System	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1984'	System	28 Sep 2020 21:32:43
User entered empty.	System	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jul 1984'	System	28 Sep 2020 21:32:43
User entered empty.	System	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (9)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1984'	System	28 Sep 2020 21:32:43
User entered empty.	System	28 Sep 2020 21:32:12

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: Cesarean section - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 14:18:00
Data point term sent to Coder	System	09 Dec 2020 14:17:22
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 14:16:59
User entered 'Cesarean SECTION' reason for change: Data Entry Error	Frances Saubon (b) (4)	09 Dec 2020 14:16:59
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:35:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:35:22
Data point term sent to Coder	System	28 Sep 2020 21:34:18
User entered 'C-section'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '24 Mar 1982'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '24 Mar 1982'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Mar 1982'	System	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1982'	System	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Mar 1982'	System	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (10)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '1982'	System	28 Sep 2020 21:33:45

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Total hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 13:30:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 13:30:40
Data point term sent to Coder	System	28 Sep 2020 21:34:20
User entered 'total hysterectomy due to fibroids'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

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Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2012'	System	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2012'	System	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2012'	System	28 Sep 2020 21:34:08

US3322388

Folder: Screening

Form: Medical History (11)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2012'	System	28 Sep 2020 21:34:08

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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Surgical and medical procedures, HLG: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Ventral hernia repair - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:36:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	28 Sep 2020 21:36:55
Data point term sent to Coder	System	28 Sep 2020 21:35:23
User entered 'ventral hernia repair'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

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Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2013'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2013'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2013'	System	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2013'	System	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2013'	System	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (12)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2013'	System	28 Sep 2020 21:34:33

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition # 12 VENTRAL HERNIA REPAIR. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 06:34:21
Query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition # 12 VENTRAL HERNIA REPAIR. If yes, please ensure only one entry is recorded. ' answered with 'This entry is not a duplicate. It was confirmed that subject received tow separate and sequential hernia repairs. ' (Site from DM).	Blessing Felix-Okoroji (b) (4)	19 Oct 2020 18:59:34
User opened query 'Per DM CLR: Please review medical diagnosis and confirm if this is a duplicate of medical condition # 12 VENTRAL HERNIA REPAIR. If yes, please ensure only one entry is recorded. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:23:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Ventral hernia repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:36:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:36:56
Data point term sent to Coder	System	28 Sep 2020 21:35:25
User entered 'ventral hernia repair'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2013'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

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Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2013'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2013'	System	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2013'	System	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2013'	System	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (13)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2013'	System	28 Sep 2020 21:34:57

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:04:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Dec 2020 16:04:49
Data point term sent to Coder	System	01 Dec 2020 16:03:34
User entered 'menopause'	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'un UNK 2012'	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2012'	System	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2012'	System	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (14)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	01 Dec 2020 16:03:03

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 07:53:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 07:53:05
Data point term sent to Coder	System	02 Dec 2020 15:18:25
User entered 'upper and lower back pain'	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'un UNK 2012'	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Elisa Moralez (b) (4)	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'Jan 2012'	System	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '2012'	System	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Medical History (15)

Generated On: 11 Aug 2021 22:17:09

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	02 Dec 2020 15:17:58

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '15:43'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '21 Sep 2020 15:43'	System	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '65.5' in	(b) (4)	
	Blessing Felix-Okoroji	28 Sep 2020 21:36:42
DataPoint set to visible.	(b) (4)	
	System	28 Sep 2020 18:21:40

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '176' lb	(b) (4) Blessing Felix-Okoroji	28 Sep 2020 21:36:42
DataPoint set to visible.	(b) (4) System	28 Sep 2020 18:21:40

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '28.90280'	System	28 Sep 2020 21:36:42
DataPoint set to visible.	System	28 Sep 2020 18:21:40

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'kg/m2'	System	28 Sep 2020 21:36:42
DataPoint set to visible.	System	28 Sep 2020 18:21:40

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '97.3' F	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '68'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'bpm'	System	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '14'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'breaths/min'	System	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '148'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '96'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	28 Sep 2020 21:36:42

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29

US3322388

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29

US3322388

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:37:06

US3322388

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:37:06

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Surgically sterile (SURGICALLY STERILE)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:17:09

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:40:13

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

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)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'I'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:17:09

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:41:22

US3322388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:18

US3322388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:18

US3322388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Clinic (Clinic)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:18

US3322388

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'VISIT1'	System	28 Sep 2020 21:51:18

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '28 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 17:48:13

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '115576'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 17:48:13

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	28 Sep 2020 17:48:13

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:39

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:39

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:39

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:39

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:51:39

US3322388

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:17:09

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji	28 Sep 2020 21:51:39
DataPoint set to visible.	(b) (4) System	28 Sep 2020 18:21:35

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '65.5' in	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '176' lb	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '65.5' in	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '176' lb	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Pre-Dose (PREDOSE)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '11:10'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '28 Sep 2020 11:10'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '97.7' F	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '59'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'bpm'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '20'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'breaths/min'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '153'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '96'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '65.5' in	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '176' lb	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Post-Dose (POSTDOSE)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '13:42'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '28 Sep 2020 13:42'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '97.2' F	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Oral (Oral)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '61'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'bpm'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '20'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'breaths/min'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '147'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '93'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	28 Sep 2020 21:53:49

US3322388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:02

US3322388

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:02

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '28 Sep 2020'	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '13:04'	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '28 Sep 2020 13:04'	System	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Frances Saubon (b) (4)	28 Sep 2020 18:26:47
User entered 'Left Arm (LEFT ARM)'	Frances Saubon (b) (4)	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'ONCE'	System	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 18:22:00

US3322388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:20

US3322388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 1 Day 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:56:11
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 1 Day 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' answered with 'Please note that a DCF has been submitted to reflect correct visit.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	23 Oct 2020 18:04:17
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 28SEP2020 is recorded under Visit 1 Day 1 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable, else clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 13:37:47
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:20

US3322388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '12:53'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:20

US3322388

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '28 Sep 2020 12:53'	System	28 Sep 2020 21:54:20

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 28SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Oct 2020 10:17:21
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 28SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Please note that a DCF has been submitted to reflect correct visit. (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 18:05:57
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 28SEP2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).		23 Oct 2020 06:35:25
User entered '28 Sep 2020'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '12:51'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '28 Sep 2020 12:51'	System	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered empty.	System	28 Sep 2020 21:54:40

US3322388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	28 Sep 2020 21:54:45

US3322388

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	28 Sep 2020 21:54:45

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:43:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '56edf0e3-b951-4c26-8e11-fedef9760ea2'	System	28 Sep 2020 18:44:47
User entered 'Yes (Y)'	System	28 Sep 2020 18:44:47

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:44:01', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '56edf0e3-b951-4c26-8e11-fedef9760ea2'	System	28 Sep 2020 18:44:47
User entered '97.2'	System	28 Sep 2020 18:44:47

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:44:20', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '56edf0e3-b951-4c26-8e11-fedef9760ea2'	System	28 Sep 2020 18:44:47
User entered 'No (N)'	System	28 Sep 2020 18:44:47

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:44:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '56edf0e3-b951-4c26-8e11-fedef9760ea2'	System	28 Sep 2020 18:44:47
User entered '28 Sep 2020 13:44'	System	28 Sep 2020 18:44:47

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 15:54'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:08', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22f9c861-199b-4f08-9033-51096a35e9b3'	System	29 Sep 2020 00:07:52
User entered 'Yes (Y)'	System	29 Sep 2020 00:07:52

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22f9c861-199b-4f08-9033-51096a35e9b3'	System	29 Sep 2020 00:07:52
User entered '97.6'	System	29 Sep 2020 00:07:52

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22f9c861-199b-4f08-9033-51096a35e9b3'	System	29 Sep 2020 00:07:52
User entered 'No (N)'	System	29 Sep 2020 00:07:52

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22f9c861-199b-4f08-9033-51096a35e9b3'	System	29 Sep 2020 00:07:52
User entered '28 Sep 2020 19:07'	System	29 Sep 2020 00:07:52

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 16:49'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 2'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:16:06', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '78268487-b67e-443a-8f28-614654293f27'	System	30 Sep 2020 04:16:31
User entered 'Yes (Y)'	System	30 Sep 2020 04:16:31

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:16:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '78268487-b67e-443a-8f28-614654293f27'	System	30 Sep 2020 04:16:31
User entered '97.5'	System	30 Sep 2020 04:16:31

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:16:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '78268487-b67e-443a-8f28-614654293f27'	System	30 Sep 2020 04:16:31
User entered 'No (N)'	System	30 Sep 2020 04:16:31

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:16:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '78268487-b67e-443a-8f28-614654293f27'	System	30 Sep 2020 04:16:31
User entered '29 Sep 2020 23:16'	System	30 Sep 2020 04:16:31

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 3'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:07:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '99377ddf-e82b-4980-9716-f591d74e5cba'	System	30 Sep 2020 18:08:40
User entered 'Yes (Y)'	System	30 Sep 2020 18:08:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '99377ddf-e82b-4980-9716-f591d74e5cba'	System	30 Sep 2020 18:08:40
User entered '97.6'	System	30 Sep 2020 18:08:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '99377ddf-e82b-4980-9716-f591d74e5cba'	System	30 Sep 2020 18:08:40
User entered 'No (N)'	System	30 Sep 2020 18:08:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '99377ddf-e82b-4980-9716-f591d74e5cba'	System	30 Sep 2020 18:08:40
User entered '30 Sep 2020 13:08'	System	30 Sep 2020 18:08:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 4'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74e0e51d-2e73-4b00-8723-9264f0ea54d0'	System	01 Oct 2020 19:12:30
User entered 'Yes (Y)'	System	01 Oct 2020 19:12:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74e0e51d-2e73-4b00-8723-9264f0ea54d0'	System	01 Oct 2020 19:12:30
User entered '98.2'	System	01 Oct 2020 19:12:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74e0e51d-2e73-4b00-8723-9264f0ea54d0'	System	01 Oct 2020 19:12:30
User entered 'No (N)'	System	01 Oct 2020 19:12:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74e0e51d-2e73-4b00-8723-9264f0ea54d0'	System	01 Oct 2020 19:12:30
User entered '01 Oct 2020 14:12'	System	01 Oct 2020 19:12:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 5'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3a966ec4-4b64-4a6a-8a4b-c9c4f2ad59b9'	System	02 Oct 2020 17:42:25
User entered 'Yes (Y)'	System	02 Oct 2020 17:42:25

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:13', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3a966ec4-4b64-4a6a-8a4b-c9c4f2ad59b9'	System	02 Oct 2020 17:42:25
User entered '97.8'	System	02 Oct 2020 17:42:25

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3a966ec4-4b64-4a6a-8a4b-c9c4f2ad59b9'	System	02 Oct 2020 17:42:25
User entered 'No (N)'	System	02 Oct 2020 17:42:25

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3a966ec4-4b64-4a6a-8a4b-c9c4f2ad59b9'	System	02 Oct 2020 17:42:25
User entered '02 Oct 2020 12:42'	System	02 Oct 2020 17:42:25

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 6'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:54:42', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'ed13aafb-ea32-4bd1-9792-6eed5720152f'	System	04 Oct 2020 15:10:40
User entered 'Yes (Y)'	System	04 Oct 2020 15:10:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'ed13aafb-ea32-4bd1-9792-6eed5720152f' User entered '97.5'	System	04 Oct 2020 15:10:40
	System	04 Oct 2020 15:10:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:06', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'ed13aafb-ea32-4bd1-9792-6eed5720152f'	System	04 Oct 2020 15:10:40
User entered 'No (N)'	System	04 Oct 2020 15:10:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'ed13aafb-ea32-4bd1-9792-6eed5720152f' User entered '03 Oct 2020 13:55'	System	04 Oct 2020 15:10:40
	System	04 Oct 2020 15:10:40

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 7'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:02:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '9f1466ab-281c-4bc7-8987-ce9496b243ef'	System	04 Oct 2020 17:02:30
User entered 'Yes (Y)'	System	04 Oct 2020 17:02:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:02:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '9f1466ab-281c-4bc7-8987-ce9496b243ef' User entered '97.7'	System	04 Oct 2020 17:02:30
	System	04 Oct 2020 17:02:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:02:23', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '9f1466ab-281c-4bc7-8987-ce9496b243ef'	System	04 Oct 2020 17:02:30
User entered 'No (N)'	System	04 Oct 2020 17:02:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:02:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '9f1466ab-281c-4bc7-8987-ce9496b243ef'	System	04 Oct 2020 17:02:30
User entered '04 Oct 2020 12:02'	System	04 Oct 2020 17:02:30

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:47:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '65c140ff-bbf7-4664-9c47-9e37f9e7dfe4'	System	28 Sep 2020 18:48:22
User entered 'None (1)'	System	28 Sep 2020 18:48:22

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:47:42', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '65c140ff-bbf7-4664-9c47-9e37f9e7dfe4'	System	28 Sep 2020 18:48:22
User entered 'No (N)'	System	28 Sep 2020 18:48:22

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:47:48', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '65c140ff-bbf7-4664-9c47-9e37f9e7dfe4'	System	28 Sep 2020 18:48:22
User entered 'No (N)'	System	28 Sep 2020 18:48:22

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:47:56', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '65c140ff-bbf7-4664-9c47-9e37f9e7dfe4'	System	28 Sep 2020 18:48:22
User entered 'None (1)'	System	28 Sep 2020 18:48:22

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:48:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '65c140ff-bbf7-4664-9c47-9e37f9e7dfe4'	System	28 Sep 2020 18:48:22
User entered '28 Sep 2020 13:48'	System	28 Sep 2020 18:48:22

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 15:54'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3e14e908-8505-44ad-9473-4bb3ecb1748c'	System	29 Sep 2020 00:08:35
User entered 'None (1)'	System	29 Sep 2020 00:08:35

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:07:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3e14e908-8505-44ad-9473-4bb3ecb1748c'	System	29 Sep 2020 00:08:35
User entered 'No (N)'	System	29 Sep 2020 00:08:35

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3e14e908-8505-44ad-9473-4bb3ecb1748c'	System	29 Sep 2020 00:08:35
User entered 'No (N)'	System	29 Sep 2020 00:08:35

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:14', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3e14e908-8505-44ad-9473-4bb3ecb1748c'	System	29 Sep 2020 00:08:35
User entered 'None (1)'	System	29 Sep 2020 00:08:35

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3e14e908-8505-44ad-9473-4bb3ecb1748c'	System	29 Sep 2020 00:08:35
User entered '28 Sep 2020 19:08'	System	29 Sep 2020 00:08:35

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 16:49'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 2'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:17:11', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '8eaf3261-cb7f-4208-9b82-a7885a2f5265'	System	30 Sep 2020 04:17:49
User entered 'None (1)'	System	30 Sep 2020 04:17:49

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:17:20', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '8eaf3261-cb7f-4208-9b82-a7885a2f5265'	System	30 Sep 2020 04:17:49
User entered 'No (N)'	System	30 Sep 2020 04:17:49

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:17:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '8eaf3261-cb7f-4208-9b82-a7885a2f5265'	System	30 Sep 2020 04:17:49
User entered 'No (N)'	System	30 Sep 2020 04:17:49

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:17:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '8eaf3261-cb7f-4208-9b82-a7885a2f5265'	System	30 Sep 2020 04:17:49
User entered 'None (1)'	System	30 Sep 2020 04:17:49

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:17:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '8eaf3261-cb7f-4208-9b82-a7885a2f5265'	System	30 Sep 2020 04:17:49
User entered '29 Sep 2020 23:17'	System	30 Sep 2020 04:17:49

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 3'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b6f7253-cd28-4382-bae1-81af17755ebb'	System	30 Sep 2020 18:09:15
User entered 'None (1)'	System	30 Sep 2020 18:09:15

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:51', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b6f7253-cd28-4382-bae1-81af17755ebb'	System	30 Sep 2020 18:09:15
User entered 'No (N)'	System	30 Sep 2020 18:09:15

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:08:56', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b6f7253-cd28-4382-bae1-81af17755ebb'	System	30 Sep 2020 18:09:15
User entered 'No (N)'	System	30 Sep 2020 18:09:15

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b6f7253-cd28-4382-bae1-81af17755ebb'	System	30 Sep 2020 18:09:15
User entered 'None (1)'	System	30 Sep 2020 18:09:15

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:13', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b6f7253-cd28-4382-bae1-81af17755ebb'	System	30 Sep 2020 18:09:15
User entered '30 Sep 2020 13:09'	System	30 Sep 2020 18:09:15

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 4'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ccaa2a2-bfb1-4546-be83-e90be4a7f6c3'	System	01 Oct 2020 19:13:29
User entered 'None (1)'	System	01 Oct 2020 19:13:29

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:49', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ccaa2a2-bfb1-4546-be83-e90be4a7f6c3'	System	01 Oct 2020 19:13:29
User entered 'No (N)'	System	01 Oct 2020 19:13:29

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:12:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ccaa2a2-bfb1-4546-be83-e90be4a7f6c3'	System	01 Oct 2020 19:13:29
User entered 'No (N)'	System	01 Oct 2020 19:13:29

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:13:12', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ccaa2a2-bfb1-4546-be83-e90be4a7f6c3'	System	01 Oct 2020 19:13:29
User entered 'None (1)'	System	01 Oct 2020 19:13:29

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:13:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ccaa2a2-bfb1-4546-be83-e90be4a7f6c3'	System	01 Oct 2020 19:13:29
User entered '01 Oct 2020 14:13'	System	01 Oct 2020 19:13:29

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 5'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd02a736d-6a1d-45d9-a374-ab5925aeb748'	System	02 Oct 2020 17:43:08
User entered 'None (1)'	System	02 Oct 2020 17:43:08

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:34', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd02a736d-6a1d-45d9-a374-ab5925aeb748'	System	02 Oct 2020 17:43:08
User entered 'No (N)'	System	02 Oct 2020 17:43:08

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:38', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd02a736d-6a1d-45d9-a374-ab5925aeb748'	System	02 Oct 2020 17:43:08
User entered 'No (N)'	System	02 Oct 2020 17:43:08

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:42:44', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd02a736d-6a1d-45d9-a374-ab5925aeb748'	System	02 Oct 2020 17:43:08
User entered 'None (1)'	System	02 Oct 2020 17:43:08

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd02a736d-6a1d-45d9-a374-ab5925aeb748'	System	02 Oct 2020 17:43:08
User entered '02 Oct 2020 12:43'	System	02 Oct 2020 17:43:08

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 6'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'beb02de4-2774-44a0-a08e-1e900336e768'	System	04 Oct 2020 15:10:42
User entered 'None (1)'	System	04 Oct 2020 15:10:42

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'beb02de4-2774-44a0-a08e-1e900336e768'	System	04 Oct 2020 15:10:42
User entered 'No (N)'	System	04 Oct 2020 15:10:42

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'beb02de4-2774-44a0-a08e-1e900336e768'	System	04 Oct 2020 15:10:42
User entered 'No (N)'	System	04 Oct 2020 15:10:42

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'beb02de4-2774-44a0-a08e-1e900336e768'	System	04 Oct 2020 15:10:42
User entered 'None (1)'	System	04 Oct 2020 15:10:42

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:55:50', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'beb02de4-2774-44a0-a08e-1e900336e768'	System	04 Oct 2020 15:10:42
User entered '03 Oct 2020 13:55'	System	04 Oct 2020 15:10:42

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 7'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:02:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '20df87bc-6933-4ca5-9e89-4bd1f471ef19'	System	04 Oct 2020 17:03:37
User entered 'None (1)'	System	04 Oct 2020 17:03:37

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:07', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '20df87bc-6933-4ca5-9e89-4bd1f471ef19'	System	04 Oct 2020 17:03:37
User entered 'No (N)'	System	04 Oct 2020 17:03:37

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '20df87bc-6933-4ca5-9e89-4bd1f471ef19'	System	04 Oct 2020 17:03:37
User entered 'No (N)'	System	04 Oct 2020 17:03:37

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '20df87bc-6933-4ca5-9e89-4bd1f471ef19'	System	04 Oct 2020 17:03:37
User entered 'None (1)'	System	04 Oct 2020 17:03:37

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '20df87bc-6933-4ca5-9e89-4bd1f471ef19'	System	04 Oct 2020 17:03:37
User entered '04 Oct 2020 12:03'	System	04 Oct 2020 17:03:37

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:57', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:33', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:38', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:41', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'None (0)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:49:50', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered 'No (N)'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T13:50:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f7b02317-653d-4c53-bbae-6cd043bb251b'	System	28 Sep 2020 18:50:10
User entered '28 Sep 2020 13:50'	System	28 Sep 2020 18:50:10

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 13:24'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 15:54'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:48', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:51', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:08:55', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'None (0)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:09:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered 'No (N)'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-28T19:09:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c75d41bb-2e66-4fbd-aebd-f6d310f77d53'	System	29 Sep 2020 00:09:09
User entered '28 Sep 2020 19:09'	System	29 Sep 2020 00:09:09

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Sep 2020 16:49'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 2'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d' User entered 'None (0)'	System	30 Sep 2020 04:18:36
	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d' User entered 'None (0)'	System	30 Sep 2020 04:18:36
	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d'	System	30 Sep 2020 04:18:36
User entered 'None (0)'	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:08', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d'	System	30 Sep 2020 04:18:36
User entered 'None (0)'	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:12', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d' User entered 'None (0)'	System	30 Sep 2020 04:18:36
	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d'	System	30 Sep 2020 04:18:36
User entered 'None (0)'	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d'	System	30 Sep 2020 04:18:36
User entered 'No (N)'	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-29T23:18:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '1e0f0cd6-6140-4eb5-a7a8-1043e2d7f92d'	System	30 Sep 2020 04:18:36
User entered '29 Sep 2020 23:18'	System	30 Sep 2020 04:18:36

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 3'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:24', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:35', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:38', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'None (0)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:44', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered 'No (N)'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-09-30T13:09:51', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c81df5e1-1b48-4d18-a03e-6caef152fe9e'	System	30 Sep 2020 18:09:56
User entered '30 Sep 2020 13:09'	System	30 Sep 2020 18:09:56

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 4'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:14', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:55', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:14:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'None (0)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:15:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered 'No (N)'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-01T14:15:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '12610c29-a920-4bf3-91a0-8f33941d09e2'	System	01 Oct 2020 19:15:18
User entered '01 Oct 2020 14:15'	System	01 Oct 2020 19:15:18

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 5'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:10', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:18', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'None (0)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered 'No (N)'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-02T12:43:35', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '7db94712-7afe-4379-af98-4422a33d693a'	System	02 Oct 2020 17:43:39
User entered '02 Oct 2020 12:43'	System	02 Oct 2020 17:43:39

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 6'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:56:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:56:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:56:50', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:56:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:56:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:57:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'None (0)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:57:06', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered 'No (N)'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-03T13:57:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '74f6053f-f345-4b33-ab0f-a2185ef6cafc'	System	04 Oct 2020 15:10:41
User entered '03 Oct 2020 13:57'	System	04 Oct 2020 15:10:41

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	28 Sep 2020 18:22:00
User entered 'Day 7'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:44', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:48', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:51', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:03:57', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'None (0)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:04:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered 'No (N)'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-04T12:04:10', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3c7cff27-2398-466e-8077-3e544cf096fd'	System	04 Oct 2020 17:04:16
User entered '04 Oct 2020 12:04'	System	04 Oct 2020 17:04:16

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 18:22:00

US3322388

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 18:22:00

US3322388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:19

US3322388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '5 Oct 2020'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:19

US3322388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:19

US3322388

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	13 Oct 2020 14:14:19

US3322388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:22

US3322388

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	13 Oct 2020 14:14:22

US3322388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:36

US3322388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '12 Oct 2020'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:36

US3322388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:36

US3322388

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	13 Oct 2020 14:14:36

US3322388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	13 Oct 2020 14:14:40

US3322388

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	13 Oct 2020 14:14:40

US3322388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	19 Oct 2020 20:08:02

US3322388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '19 Oct 2020'	Elisa Moralez (b) (4)	19 Oct 2020 20:08:02

US3322388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	19 Oct 2020 20:08:02

US3322388

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	19 Oct 2020 20:08:02

US3322388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	19 Oct 2020 20:07:52

US3322388

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	19 Oct 2020 20:07:52

US3322388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:03:02

US3322388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:03:02

US3322388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:03:02

US3322388

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'VISIT2'	System	26 Oct 2020 19:03:02

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Pre-Dose (PREDOSE)'		26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '11:35'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '26 Oct 2020 11:35'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '67'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'bpm'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '16'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'breaths/min'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '136'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '88'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Post-Dose (POSTDOSE)'		26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '13:46'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '26 Oct 2020 13:46'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '71'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'bpm'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '14'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'breaths/min'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '121'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '76'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	26 Oct 2020 19:10:46

US3322388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:11:30

US3322388

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:11:30

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'MRNA-1273 OR PLACEBO'	System	26 Oct 2020 18:33:13

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '13:01'	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '26 Oct 2020 13:01'	System	26 Oct 2020 18:33:13

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Right Arm (RIGHT ARM)'	(b) (4) khorshid Amirkhosravi	26 Oct 2020 18:33:13
	(b) (4)	

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'ONCE'	System	26 Oct 2020 18:33:13

US3322388

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'INTRAMUSCULAR'	System	26 Oct 2020 18:33:13

US3322388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:09

US3322388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:09

US3322388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '12:55'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:09

US3322388

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '26 Oct 2020 12:55'	System	26 Oct 2020 19:12:09

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:17:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '12:50'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '26 Oct 2020 12:50'	System	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered empty.	System	26 Oct 2020 19:12:48

US3322388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 19:12:56

US3322388

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '1'	System	26 Oct 2020 19:12:56

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:49:44', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22139e76-fb21-4685-a328-dee33f2a2715'	System	26 Oct 2020 18:50:10
User entered 'Yes (Y)'	System	26 Oct 2020 18:50:10

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:49:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22139e76-fb21-4685-a328-dee33f2a2715'	System	26 Oct 2020 18:50:10
User entered '96.8'	System	26 Oct 2020 18:50:10

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:49:58', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22139e76-fb21-4685-a328-dee33f2a2715'	System	26 Oct 2020 18:50:10
User entered 'No (N)'	System	26 Oct 2020 18:50:10

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:04', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '22139e76-fb21-4685-a328-dee33f2a2715'	System	26 Oct 2020 18:50:10
User entered '26 Oct 2020 13:50'	System	26 Oct 2020 18:50:10

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 13:21'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 15:51'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:12:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '986ad0d4-c7c5-4eec-bcf4-a163f9ab0361'	System	26 Oct 2020 23:12:58
User entered 'Yes (Y)'	System	26 Oct 2020 23:12:58

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:12:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '986ad0d4-c7c5-4eec-bcf4-a163f9ab0361' User entered '97.4'	System	26 Oct 2020 23:12:58
	System	26 Oct 2020 23:12:58

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:12:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '986ad0d4-c7c5-4eec-bcf4-a163f9ab0361'	System	26 Oct 2020 23:12:58
User entered 'No (N)'	System	26 Oct 2020 23:12:58

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:12:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '986ad0d4-c7c5-4eec-bcf4-a163f9ab0361'	System	26 Oct 2020 23:12:58
User entered '26 Oct 2020 18:12'	System	26 Oct 2020 23:12:58

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 16:46'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 2'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b750e174-6a4a-43c6-8f01-577628b9fff5'	System	27 Oct 2020 22:21:47
User entered 'Yes (Y)'	System	27 Oct 2020 22:21:47

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:34', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b750e174-6a4a-43c6-8f01-577628b9fff5' User entered '96.8'	System	27 Oct 2020 22:21:47
	System	27 Oct 2020 22:21:47

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b750e174-6a4a-43c6-8f01-577628b9fff5'	System	27 Oct 2020 22:21:47
User entered 'No (N)'	System	27 Oct 2020 22:21:47

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b750e174-6a4a-43c6-8f01-577628b9fff5'	System	27 Oct 2020 22:21:47
User entered '27 Oct 2020 17:21'	System	27 Oct 2020 22:21:47

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 3'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:42:49', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd117d0f8-6c1d-4f84-a8f7-901fd4090ba7'	System	29 Oct 2020 10:43:18
User entered 'Yes (Y)'	System	29 Oct 2020 10:43:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd117d0f8-6c1d-4f84-a8f7-901fd4090ba7'	System	29 Oct 2020 10:43:18
User entered '97.5'	System	29 Oct 2020 10:43:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd117d0f8-6c1d-4f84-a8f7-901fd4090ba7'	System	29 Oct 2020 10:43:18
User entered 'No (N)'	System	29 Oct 2020 10:43:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:13', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd117d0f8-6c1d-4f84-a8f7-901fd4090ba7'	System	29 Oct 2020 10:43:18
User entered '29 Oct 2020 05:43'	System	29 Oct 2020 10:43:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 4'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:31:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd63778cc-5040-453c-afde-55d9ec8d59a0'	System	29 Oct 2020 19:32:23
User entered 'Yes (Y)'	System	29 Oct 2020 19:32:23

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:04', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd63778cc-5040-453c-afde-55d9ec8d59a0'	System	29 Oct 2020 19:32:23
User entered '97.4'	System	29 Oct 2020 19:32:23

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd63778cc-5040-453c-afde-55d9ec8d59a0'	System	29 Oct 2020 19:32:23
User entered 'No (N)'	System	29 Oct 2020 19:32:23

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd63778cc-5040-453c-afde-55d9ec8d59a0'	System	29 Oct 2020 19:32:23
User entered '29 Oct 2020 14:32'	System	29 Oct 2020 19:32:23

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 5'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:28:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '47e7c450-7a9f-4361-9e3d-649ce4dc025d'	System	30 Oct 2020 23:29:18
User entered 'Yes (Y)'	System	30 Oct 2020 23:29:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '47e7c450-7a9f-4361-9e3d-649ce4dc025d'	System	30 Oct 2020 23:29:18
User entered '97.6'	System	30 Oct 2020 23:29:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '47e7c450-7a9f-4361-9e3d-649ce4dc025d'	System	30 Oct 2020 23:29:18
User entered 'No (N)'	System	30 Oct 2020 23:29:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:14', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '47e7c450-7a9f-4361-9e3d-649ce4dc025d'	System	30 Oct 2020 23:29:18
User entered '30 Oct 2020 18:29'	System	30 Oct 2020 23:29:18

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 6'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:53:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5c024ed8-4edb-4e6b-8bc7-347b2eb6afd4'	System	31 Oct 2020 18:53:56
User entered 'Yes (Y)'	System	31 Oct 2020 18:53:56

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:53:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5c024ed8-4edb-4e6b-8bc7-347b2eb6afd4'	System	31 Oct 2020 18:53:56
User entered '97.4'	System	31 Oct 2020 18:53:56

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:53:48', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5c024ed8-4edb-4e6b-8bc7-347b2eb6afd4'	System	31 Oct 2020 18:53:56
User entered 'No (N)'	System	31 Oct 2020 18:53:56

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:53:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5c024ed8-4edb-4e6b-8bc7-347b2eb6afd4'	System	31 Oct 2020 18:53:56
User entered '31 Oct 2020 13:53'	System	31 Oct 2020 18:53:56

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 7'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:20:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '97301373-8fcb-4391-a415-ee40e83a4c84'	System	01 Nov 2020 20:21:01
User entered 'Yes (Y)'	System	01 Nov 2020 20:21:01

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:20:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '97301373-8fcb-4391-a415-ee40e83a4c84'	System	01 Nov 2020 20:21:01
User entered '97.6'	System	01 Nov 2020 20:21:01

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:20:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '97301373-8fcb-4391-a415-ee40e83a4c84'	System	01 Nov 2020 20:21:01
User entered 'No (N)'	System	01 Nov 2020 20:21:01

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:20:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '97301373-8fcb-4391-a415-ee40e83a4c84'	System	01 Nov 2020 20:21:01
User entered '01 Nov 2020 14:20'	System	01 Nov 2020 20:21:01

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:23', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2cb4a6c7-80f5-48e7-b51c-45c578f2a425'	System	26 Oct 2020 18:51:04
User entered 'None (1)'	System	26 Oct 2020 18:51:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:34', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2cb4a6c7-80f5-48e7-b51c-45c578f2a425'	System	26 Oct 2020 18:51:04
User entered 'No (N)'	System	26 Oct 2020 18:51:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2cb4a6c7-80f5-48e7-b51c-45c578f2a425'	System	26 Oct 2020 18:51:04
User entered 'No (N)'	System	26 Oct 2020 18:51:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2cb4a6c7-80f5-48e7-b51c-45c578f2a425'	System	26 Oct 2020 18:51:04
User entered 'None (1)'	System	26 Oct 2020 18:51:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:50:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2cb4a6c7-80f5-48e7-b51c-45c578f2a425'	System	26 Oct 2020 18:51:04
User entered '26 Oct 2020 13:50'	System	26 Oct 2020 18:51:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 13:21'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 15:51'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '63020550-f029-4616-b9f2-da815595af5f'	System	26 Oct 2020 23:13:34
User entered 'None (1)'	System	26 Oct 2020 23:13:34

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '63020550-f029-4616-b9f2-da815595af5f'	System	26 Oct 2020 23:13:34
User entered 'No (N)'	System	26 Oct 2020 23:13:34

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '63020550-f029-4616-b9f2-da815595af5f'	System	26 Oct 2020 23:13:34
User entered 'No (N)'	System	26 Oct 2020 23:13:34

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:23', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '63020550-f029-4616-b9f2-da815595af5f'	System	26 Oct 2020 23:13:34
User entered 'None (1)'	System	26 Oct 2020 23:13:34

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '63020550-f029-4616-b9f2-da815595af5f' User entered '26 Oct 2020 18:13'	System	26 Oct 2020 23:13:34
	System	26 Oct 2020 23:13:34

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 16:46'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 2'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:50', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '10d2f813-11a8-4746-9945-3cdd5c5916f8'	System	27 Oct 2020 22:22:11
User entered 'None (1)'	System	27 Oct 2020 22:22:11

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '10d2f813-11a8-4746-9945-3cdd5c5916f8'	System	27 Oct 2020 22:22:11
User entered 'No (N)'	System	27 Oct 2020 22:22:11

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:21:57', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '10d2f813-11a8-4746-9945-3cdd5c5916f8'	System	27 Oct 2020 22:22:11
User entered 'No (N)'	System	27 Oct 2020 22:22:11

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '10d2f813-11a8-4746-9945-3cdd5c5916f8'	System	27 Oct 2020 22:22:11
User entered 'None (1)'	System	27 Oct 2020 22:22:11

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:06', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '10d2f813-11a8-4746-9945-3cdd5c5916f8'	System	27 Oct 2020 22:22:11
User entered '27 Oct 2020 17:22'	System	27 Oct 2020 22:22:11

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 3'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '27fd6190-3daa-4a12-999f-f8fcf64a40b0'	System	29 Oct 2020 10:44:04
User entered 'None (1)'	System	29 Oct 2020 10:44:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '27fd6190-3daa-4a12-999f-f8fcf64a40b0'	System	29 Oct 2020 10:44:04
User entered 'No (N)'	System	29 Oct 2020 10:44:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '27fd6190-3daa-4a12-999f-f8fcf64a40b0'	System	29 Oct 2020 10:44:04
User entered 'No (N)'	System	29 Oct 2020 10:44:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:43:49', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '27fd6190-3daa-4a12-999f-f8fcf64a40b0'	System	29 Oct 2020 10:44:04
User entered 'None (1)'	System	29 Oct 2020 10:44:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '27fd6190-3daa-4a12-999f-f8fcf64a40b0'	System	29 Oct 2020 10:44:04
User entered '29 Oct 2020 05:44'	System	29 Oct 2020 10:44:04

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 4'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:24', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7dbc949-f57e-470b-82c5-dc2e081ed79a'	System	29 Oct 2020 19:32:46
User entered 'None (1)'	System	29 Oct 2020 19:32:46

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7dbc949-f57e-470b-82c5-dc2e081ed79a'	System	29 Oct 2020 19:32:46
User entered 'No (N)'	System	29 Oct 2020 19:32:46

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:35', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7dbc949-f57e-470b-82c5-dc2e081ed79a'	System	29 Oct 2020 19:32:46
User entered 'No (N)'	System	29 Oct 2020 19:32:46

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7dbc949-f57e-470b-82c5-dc2e081ed79a'	System	29 Oct 2020 19:32:46
User entered 'None (1)'	System	29 Oct 2020 19:32:46

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:42', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7dbc949-f57e-470b-82c5-dc2e081ed79a'	System	29 Oct 2020 19:32:46
User entered '29 Oct 2020 14:32'	System	29 Oct 2020 19:32:46

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 5'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:20', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ea27eb5-6bb9-4bb0-a0eb-daae3daf0e0e'	System	30 Oct 2020 23:29:56
User entered 'None (1)'	System	30 Oct 2020 23:29:56

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ea27eb5-6bb9-4bb0-a0eb-daae3daf0e0e'	System	30 Oct 2020 23:29:56
User entered 'No (N)'	System	30 Oct 2020 23:29:56

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ea27eb5-6bb9-4bb0-a0eb-daae3daf0e0e'	System	30 Oct 2020 23:29:56
User entered 'No (N)'	System	30 Oct 2020 23:29:56

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ea27eb5-6bb9-4bb0-a0eb-daae3daf0e0e'	System	30 Oct 2020 23:29:56
User entered 'None (1)'	System	30 Oct 2020 23:29:56

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:29:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5ea27eb5-6bb9-4bb0-a0eb-daae3daf0e0e'	System	30 Oct 2020 23:29:56
User entered '30 Oct 2020 18:29'	System	30 Oct 2020 23:29:56

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 6'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:53:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b79807d-ff8f-4778-8564-bb5deace0fb3'	System	31 Oct 2020 18:54:42
User entered 'None (1)'	System	31 Oct 2020 18:54:42

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:54:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b79807d-ff8f-4778-8564-bb5deace0fb3'	System	31 Oct 2020 18:54:42
User entered 'No (N)'	System	31 Oct 2020 18:54:42

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:54:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b79807d-ff8f-4778-8564-bb5deace0fb3'	System	31 Oct 2020 18:54:42
User entered 'No (N)'	System	31 Oct 2020 18:54:42

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:54:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b79807d-ff8f-4778-8564-bb5deace0fb3'	System	31 Oct 2020 18:54:42
User entered 'None (1)'	System	31 Oct 2020 18:54:42

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:54:38', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2b79807d-ff8f-4778-8564-bb5deace0fb3'	System	31 Oct 2020 18:54:42
User entered '31 Oct 2020 13:54'	System	31 Oct 2020 18:54:42

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 7'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:21:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'cc06676f-79b1-4d7b-80f3-7fb9c8114119'	System	01 Nov 2020 20:21:26
User entered 'None (1)'	System	01 Nov 2020 20:21:26

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:21:10', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'cc06676f-79b1-4d7b-80f3-7fb9c8114119'	System	01 Nov 2020 20:21:26
User entered 'No (N)'	System	01 Nov 2020 20:21:26

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:21:13', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'cc06676f-79b1-4d7b-80f3-7fb9c8114119'	System	01 Nov 2020 20:21:26
User entered 'No (N)'	System	01 Nov 2020 20:21:26

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:21:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'cc06676f-79b1-4d7b-80f3-7fb9c8114119'	System	01 Nov 2020 20:21:26
User entered 'None (1)'	System	01 Nov 2020 20:21:26

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:21:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'cc06676f-79b1-4d7b-80f3-7fb9c8114119'	System	01 Nov 2020 20:21:26
User entered '01 Nov 2020 14:21'	System	01 Nov 2020 20:21:26

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:08', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:22', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:27', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'None (0)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered 'No (N)'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T13:51:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4d4ad3ad-bf13-41c9-aa2a-5539c59469f2'	System	26 Oct 2020 18:51:39
User entered '26 Oct 2020 13:51'	System	26 Oct 2020 18:51:39

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 13:21'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 15:51'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 1, after vaccination (at home)'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:45', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:49', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:52', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:55', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:57', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:13:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'None (0)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:14:04', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered 'No (N)'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-26T18:14:07', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'edcbf1d5-1d5f-4e11-94e2-ec7950bb86dc'	System	26 Oct 2020 23:14:11
User entered '26 Oct 2020 18:14'	System	26 Oct 2020 23:14:11

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '26 Oct 2020 16:46'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 2'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:11', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:18', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:26', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'None (0)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered 'No (N)'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-27T17:22:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '94652b97-e570-4045-bf84-b899de1e41d6'	System	27 Oct 2020 22:22:46
User entered '27 Oct 2020 17:22'	System	27 Oct 2020 22:22:46

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '27 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 3'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:08', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:11', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:34', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:44', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'None (0)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:50', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered 'No (N)'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T05:44:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4fca39c2-4c4b-4261-aae0-c761bb85b155'	System	29 Oct 2020 10:44:59
User entered '29 Oct 2020 05:44'	System	29 Oct 2020 10:44:59

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '28 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 4'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:49', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:32:52', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:33:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:33:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:33:09', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'None (0)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:33:12', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered 'No (N)'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-29T14:33:17', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '89651073-67c8-477b-b720-cff62e61f813'	System	29 Oct 2020 19:33:21
User entered '29 Oct 2020 14:33'	System	29 Oct 2020 19:33:21

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '29 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 5'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:30:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:30:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:30:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:31:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:31:18', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:31:20', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'None (0)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:31:26', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered 'No (N)'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-30T18:31:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b4b35dc7-cd18-4d49-b388-73bd238c8901'	System	30 Oct 2020 23:31:32
User entered '30 Oct 2020 18:31'	System	30 Oct 2020 23:31:32

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '30 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 6'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:55:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d' User entered 'None (0)'	System	31 Oct 2020 18:56:27
	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:55:37', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d'	System	31 Oct 2020 18:56:27
User entered 'None (0)'	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:55:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d' User entered 'None (0)'	System	31 Oct 2020 18:56:27
	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:55:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d' User entered 'None (0)'	System	31 Oct 2020 18:56:27
	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:56:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d' User entered 'None (0)'	System	31 Oct 2020 18:56:27
	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:56:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d'	System	31 Oct 2020 18:56:27
User entered 'None (0)'	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:56:10', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcbcd755d'	System	31 Oct 2020 18:56:27
User entered 'No (N)'	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-10-31T13:56:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '3cfa8ac4-fab7-44cc-9171-fe6dcabcd755d'	System	31 Oct 2020 18:56:27
User entered '31 Oct 2020 13:56'	System	31 Oct 2020 18:56:27

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '31 Oct 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
Data entry locked.	System	26 Oct 2020 18:33:13
User entered 'Day 7'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:16', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:24', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:43', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:48', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'None (0)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:52', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered 'No (N)'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-01T14:22:56', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '31b3ee4f-1505-42be-98cb-7a2fcc563a67'	System	01 Nov 2020 20:22:57
User entered '01 Nov 2020 14:22'	System	01 Nov 2020 20:22:57

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '01 Nov 2020 12:00'	System	26 Oct 2020 18:33:13

US3322388

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:17:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 13:17:44
User entered '02 Nov 2020 11:59'	System	26 Oct 2020 18:33:13

US3322388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Nov 2020 19:04:27

US3322388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '02 Nov 2020'	Elisa Moralez (b) (4)	02 Nov 2020 19:04:27

US3322388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	02 Nov 2020 19:04:27

US3322388

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	02 Nov 2020 19:04:27

US3322388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	02 Nov 2020 19:04:32

US3322388

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	02 Nov 2020 19:04:32

US3322388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 14:36:19

US3322388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '09 Nov 2020'	Elisa Moralez (b) (4)	10 Nov 2020 14:36:19

US3322388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	10 Nov 2020 14:36:19

US3322388

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	10 Nov 2020 14:36:19

US3322388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	10 Nov 2020 14:36:22

US3322388

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	10 Nov 2020 14:36:22

US3322388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Nov 2020 16:07:48

US3322388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '16 Nov 2020'	Elisa Moralez (b) (4)	16 Nov 2020 16:07:48

US3322388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	16 Nov 2020 16:07:48

US3322388

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	16 Nov 2020 16:07:48

US3322388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Nov 2020 16:07:54

US3322388

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '1'	System	16 Nov 2020 16:07:54

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Moez Talpur (b) (4)	07 Dec 2020 19:56:24

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 15:48:10
User closed query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the V3D57 28 days (-3/+7 days) after vaccination from V2D29. Exposure date from V2D29 is 26 Oct 2020 and V3D57 date is 07 Dec 2020 which is more than 35 days. Please reconcile and update as needed, else provide clarification.' (Site from DM).		09 Dec 2020 15:48:08
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Frances Saubon (b) (4)	08 Dec 2020 18:42:43
answered with 'Per source, subject was initially scheduled for 20-Nov-2020 however due to ongoing nasal congestion and rhinorrhea Day 57/Visit 3 was converted as Illness visit.' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Dec 2020 18:39:53
User entered '07 Dec 2020' reason for change: Data Entry Error	Frances Saubon (b) (4)	08 Dec 2020 18:39:53
Query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the V3D57 28 days (-3/+7 days) after vaccination from V2D29. Exposure date from V2D29 is 26 Oct 2020 and V3D57 date is 07 Dec 2020 which is more than 35 days. Please reconcile and update as needed, else provide clarification.' answered with 'Clarification per previous query response, there is no protocol deviation occurred as the subject was still in the convalescent period as per communication received from Sponsor.' (Site from DM).	Frances Saubon (b) (4)	08 Dec 2020 18:39:42
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 16:13:26

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per CDM Re-query: Site response noted. According to Protocol, it is expected to perform the V3D57 28 days (-3/+7 days) after vaccination from V2D29. Exposure date from V2D29 is 26 Oct 2020 and V3D57 date is 07 Dec 2020 which is more than 35 days. Please reconcile and update as needed, else provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 16:13:20
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Moez Talpur (b) (4)	07 Dec 2020 19:57:27
answered with 'Per source - Addendum to previous progress note, no protocol deviation occurred on V3 conducted on 07-DEC-2020. Per study manager,' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Dec 2020 19:56:24
User entered '7 Dec 2020'	Moez Talpur (b) (4)	07 Dec 2020 19:56:24
	(b) (4)	

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Clinic (Clinic)'	Moez Talpur (b) (4)	07 Dec 2020 19:56:24

US3322388

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'VISIT3'	System	07 Dec 2020 19:56:24

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '7 Dec 2020'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '11:02'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '7 Dec 2020 11:02'	System	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '97.8' F	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Oral (Oral)'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered empty.	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '68'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'bpm'	System	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '16'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'breaths/min'	System	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '158'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '80'	Moez Talpur (b) (4)	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'mmHg'	System	07 Dec 2020 19:58:42

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05

US3322388

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05

US3322388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Moez Talpur (b) (4)	07 Dec 2020 19:58:56

US3322388

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '7 Dec 2020'	Moez Talpur (b) (4)	07 Dec 2020 19:58:56

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Moez Talpur (b) (4)	07 Dec 2020 19:59:13

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07DEC2020 is recorded under Visit3 Day57 visit in EDC, however the same sample is reported with date 30NOV2020 in PPD Central lab. Please confirm the correct date and update EDC or PPD portal. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 05:18:47
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07DEC2020 is recorded under Visit3 Day57 visit in EDC, however the same sample is reported with date 30NOV2020 in PPD Central lab. Please confirm the correct date and update EDC or PPD portal. Else Clarify, Thank you.' answered with 'Noted, a DCF will be submitted to reflect the correct collection date: 07-DEC-2020.' (Site from DM).	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:26:40
User entered '07 Dec 2020' reason for change: Data Entry Error	Frances Saubon (b) (4) (b) (4)	20 Dec 2020 04:26:06
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07DEC2020 is recorded under Visit3 Day57 visit in EDC, however the same sample is reported with date 30NOV2020 in PPD Central lab. Please confirm the correct date and update EDC or PPD portal. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:14:32
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07DEC2020 is recorded under Visit3 Day57 visit in EDC, however the same is reported under Visit3 Day57 Visit with date 30NOV2020 in PPD Central lab. Please confirm the correct date and update EDC or PPD portal. Else Clarify, Thank you.' canceled (Site from DM).		16 Dec 2020 08:13:53

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 07DEC2020 is recorded under Visit3 Day57 visit in EDC, however the same is reported under Visit3 Day57 Visit with date 30NOV2020 in PPD Central lab. Please confirm the correct date and update EDC or PPD portal. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 08:13:45
User entered '7 Dec 2020'	Moez Talpur (b) (4) (b) (4)	07 Dec 2020 19:59:13

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered '11:57'	Moez Talpur (b) (4)	07 Dec 2020 19:59:13

US3322388

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '07 Dec 2020 11:57'	System	20 Dec 2020 04:26:06
User entered '7 Dec 2020 11:57'	System	07 Dec 2020 19:59:13

US3322388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:35
User entered 'Yes (Y)'	Moez Talpur (b) (4)	07 Dec 2020 19:59:27

US3322388

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered '1'	System	07 Dec 2020 19:59:27

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-11-26T18:17:15', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered 'Yes (Y)'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-11-26T18:17:23', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered 'No (N)'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-26T18:17:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered 'No (N)'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-26T18:17:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered 'Yes (Y)'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-26T18:17:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-11-26T18:18:10', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '4a971311-dfcb-462f-8789-a7aae60a599d'	System	27 Nov 2020 00:18:21
User entered '26 Nov 2020 18:18:10'	System	27 Nov 2020 00:18:21

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-12-04T07:44:07', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '6d2672b9-9b18-4323-83cf-facb5bc13259'	System	04 Dec 2020 13:44:33
User entered 'No (N)'	System	04 Dec 2020 13:44:33

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-12-04T07:44:21', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '6d2672b9-9b18-4323-83cf-facb5bc13259'	System	04 Dec 2020 13:44:33
User entered 'No (N)'	System	04 Dec 2020 13:44:33

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-12-04T07:44:29', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '6d2672b9-9b18-4323-83cf-facb5bc13259'	System	04 Dec 2020 13:44:33
User entered '04 Dec 2020 07:44:29'	System	04 Dec 2020 13:44:33

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-12-09T11:55:01', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b3125591-6f85-4e06-9854-f41880bad760'	System	09 Dec 2020 17:55:14
User entered 'No (N)'	System	09 Dec 2020 17:55:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-12-09T11:55:06', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b3125591-6f85-4e06-9854-f41880bad760'	System	09 Dec 2020 17:55:14
User entered 'No (N)'	System	09 Dec 2020 17:55:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-12-09T11:55:11', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'b3125591-6f85-4e06-9854-f41880bad760'	System	09 Dec 2020 17:55:14
User entered '09 Dec 2020 11:55:11'	System	09 Dec 2020 17:55:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-12-17T12:21:31', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'fb52efee-cdb0-46c5-b778-904ad6999cdb'	System	17 Dec 2020 18:21:45
User entered 'No (N)'	System	17 Dec 2020 18:21:45

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-12-17T12:21:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'fb52efee-cdb0-46c5-b778-904ad6999cdb'	System	17 Dec 2020 18:21:45
User entered 'No (N)'	System	17 Dec 2020 18:21:45

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-12-17T12:21:40', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'fb52efee-cdb0-46c5-b778-904ad6999cdb' User entered '17 Dec 2020 12:21:40'	System	17 Dec 2020 18:21:45
	System	17 Dec 2020 18:21:45

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-12-24T13:12:19', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd50b66a8-3014-4b99-8ec0-514eea712a1b'	System	24 Dec 2020 19:13:06
User entered 'No (N)'	System	24 Dec 2020 19:13:06

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-12-24T13:12:57', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd50b66a8-3014-4b99-8ec0-514eea712a1b'	System	24 Dec 2020 19:13:06
User entered 'No (N)'	System	24 Dec 2020 19:13:06

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-12-24T13:13:02', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'd50b66a8-3014-4b99-8ec0-514eea712a1b'	System	24 Dec 2020 19:13:06
User entered '24 Dec 2020 13:13:02'	System	24 Dec 2020 19:13:06

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2020-12-30T17:39:18', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7ae2a48-f883-4cff-97a0-6484a6632f15'	System	30 Dec 2020 23:39:42
User entered 'No (N)'	System	30 Dec 2020 23:39:42

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2020-12-30T17:39:28', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7ae2a48-f883-4cff-97a0-6484a6632f15'	System	30 Dec 2020 23:39:42
User entered 'No (N)'	System	30 Dec 2020 23:39:42

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2020-12-30T17:39:36', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e7ae2a48-f883-4cff-97a0-6484a6632f15'	System	30 Dec 2020 23:39:42
User entered '30 Dec 2020 17:39:36'	System	30 Dec 2020 23:39:42

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-01-07T14:42:54', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5e8888a8-9476-4cec-95ad-07c5622ee6f7'	System	07 Jan 2021 20:43:37
User entered 'No (N)'	System	07 Jan 2021 20:43:37

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-01-07T14:43:05', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5e888a8-9476-4cec-95ad-07c5622ee6f7'	System	07 Jan 2021 20:43:37
User entered 'No (N)'	System	07 Jan 2021 20:43:37

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-01-07T14:43:32', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5e8888a8-9476-4cec-95ad-07c5622ee6f7' User entered '07 Jan 2021 14:43:32'	System	07 Jan 2021 20:43:37

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-01-14T17:30:18', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '29f1a720-5449-44c7-824c-20400f376400'	System	14 Jan 2021 23:30:36
User entered 'No (N)'	System	14 Jan 2021 23:30:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-01-14T17:30:26', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '29f1a720-5449-44c7-824c-20400f376400'	System	14 Jan 2021 23:30:36
User entered 'No (N)'	System	14 Jan 2021 23:30:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-01-14T17:30:30', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '29f1a720-5449-44c7-824c-20400f376400'	System	14 Jan 2021 23:30:36
User entered '14 Jan 2021 17:30:30'	System	14 Jan 2021 23:30:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-01-20T14:09:41', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f98b977d-b9b7-4f67-b249-2c832f31e0b0'	System	20 Jan 2021 20:10:11
User entered 'No (N)'	System	20 Jan 2021 20:10:11

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-01-20T14:09:46', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f98b977d-b9b7-4f67-b249-2c832f31e0b0'	System	20 Jan 2021 20:10:11
User entered 'No (N)'	System	20 Jan 2021 20:10:11

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-01-20T14:10:07', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'f98b977d-b9b7-4f67-b249-2c832f31e0b0' User entered '20 Jan 2021 14:10:07'	System	20 Jan 2021 20:10:11

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-01-27T14:51:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5367780f-774b-435c-aeee-9f85b90d51bc'	System	27 Jan 2021 20:52:07
User entered 'No (N)'	System	27 Jan 2021 20:52:07

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-01-27T14:51:59', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5367780f-774b-435c-aeee-9f85b90d51bc'	System	27 Jan 2021 20:52:07
User entered 'No (N)'	System	27 Jan 2021 20:52:07

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-01-27T14:52:03', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '5367780f-774b-435c-aeee-9f85b90d51bc' User entered '27 Jan 2021 14:52:03'	System	27 Jan 2021 20:52:07

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-02-04T08:37:47', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '71c32061-1e4e-4599-b778-a5b8a0d988e7'	System	04 Feb 2021 14:38:14
User entered 'No (N)'	System	04 Feb 2021 14:38:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-02-04T08:37:55', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '71c32061-1e4e-4599-b778-a5b8a0d988e7'	System	04 Feb 2021 14:38:14
User entered 'No (N)'	System	04 Feb 2021 14:38:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-02-04T08:38:08', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '71c32061-1e4e-4599-b778-a5b8a0d988e7'	System	04 Feb 2021 14:38:14
User entered '04 Feb 2021 08:38:08'	System	04 Feb 2021 14:38:14

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-02-10T21:16:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'aa27c7f3-8fe9-43bc-94ff-56a003c0cea1'	System	11 Feb 2021 03:17:04
User entered 'No (N)'	System	11 Feb 2021 03:17:04

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-02-10T21:16:53', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'aa27c7f3-8fe9-43bc-94ff-56a003c0cea1'	System	11 Feb 2021 03:17:04
User entered 'No (N)'	System	11 Feb 2021 03:17:04

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-02-10T21:17:01', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'aa27c7f3-8fe9-43bc-94ff-56a003c0cea1'	System	11 Feb 2021 03:17:04
User entered '10 Feb 2021 21:17:01'	System	11 Feb 2021 03:17:04

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-02-17T18:47:25', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '09a3828b-c1db-4170-bf60-b15d7c268a94'	System	18 Feb 2021 00:47:44
User entered 'No (N)'	System	18 Feb 2021 00:47:44

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-02-17T18:47:33', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '09a3828b-c1db-4170-bf60-b15d7c268a94'	System	18 Feb 2021 00:47:44
User entered 'No (N)'	System	18 Feb 2021 00:47:44

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-02-17T18:47:39', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '09a3828b-c1db-4170-bf60-b15d7c268a94'	System	18 Feb 2021 00:47:44
User entered '17 Feb 2021 18:47:39'	System	18 Feb 2021 00:47:44

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-02-24T08:28:37-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'efe66399-47d6-4a28-99a7-087cfd7705c' User entered 'No (N)'	System	24 Feb 2021 14:29:01
	System	24 Feb 2021 14:29:01

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-02-24T08:28:44-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'efe66399-47d6-4a28-99a7-087cfd7705c'	System	24 Feb 2021 14:29:01
User entered 'No (N)'	System	24 Feb 2021 14:29:01

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-02-24T08:28:55-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'efe66399-47d6-4a28-99a7-087cfd7705c' User entered '24 Feb 2021 08:28:55'	System	24 Feb 2021 14:29:01
	System	24 Feb 2021 14:29:01

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-03-03T18:47:08-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '55df2617-5474-40e3-8038-19e174b6be96'	System	04 Mar 2021 00:47:22
User entered 'No (N)'	System	04 Mar 2021 00:47:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-03-03T18:47:12-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '55df2617-5474-40e3-8038-19e174b6be96'	System	04 Mar 2021 00:47:22
User entered 'No (N)'	System	04 Mar 2021 00:47:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-03T18:47:17-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '55df2617-5474-40e3-8038-19e174b6be96'	System	04 Mar 2021 00:47:22
User entered '03 Mar 2021 18:47:17'	System	04 Mar 2021 00:47:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-03-10T14:31:45-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0473f753-fe35-4afd-aafe-09fedfdfedca' User entered 'No (N)'	System	10 Mar 2021 20:31:58

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-03-10T14:31:50-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0473f753-fe35-4afd-aafe-09fedfdfedca' User entered 'No (N)'	System	10 Mar 2021 20:31:58

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-10T14:31:55-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0473f753-fe35-4afd-aafe-09fedfdfedca' User entered '10 Mar 2021 14:31:55'	System	10 Mar 2021 20:31:58
	System	10 Mar 2021 20:31:58

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-03-18T01:41:00-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'a8be1895-0eae-4344-b387-82cf55ec56b3'	System	18 Mar 2021 06:41:20
User entered 'No (N)'	System	18 Mar 2021 06:41:20

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-03-18T01:41:05-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'a8be1895-0eae-4344-b387-82cf55ec56b3'	System	18 Mar 2021 06:41:20
User entered 'No (N)'	System	18 Mar 2021 06:41:20

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-18T01:41:13-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'a8be1895-0eae-4344-b387-82cf55ec56b3'	System	18 Mar 2021 06:41:20
User entered '18 Mar 2021 01:41:13'	System	18 Mar 2021 06:41:20

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-03-24T17:44:18-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e2b098ac-0183-4dd5-9d82-6a672095ab3b'	System	24 Mar 2021 22:44:36
User entered 'No (N)'	System	24 Mar 2021 22:44:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-03-24T17:44:24-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e2b098ac-0183-4dd5-9d82-6a672095ab3b'	System	24 Mar 2021 22:44:36
User entered 'No (N)'	System	24 Mar 2021 22:44:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-24T17:44:29-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e2b098ac-0183-4dd5-9d82-6a672095ab3b' User entered '24 Mar 2021 17:44:29'	System	24 Mar 2021 22:44:36
	System	24 Mar 2021 22:44:36

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-04-01T16:08:10-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'be9ce0a3-95a7-489a-939a-0022d832cfb0' User entered 'Yes (Y)'	System	01 Apr 2021 21:09:22
	System	01 Apr 2021 21:09:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-04-01T16:08:29-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'be9ce0a3-95a7-489a-939a-0022d832cfb0'	System	01 Apr 2021 21:09:22
User entered 'No (N)'	System	01 Apr 2021 21:09:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-01T16:09:04-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'be9ce0a3-95a7-489a-939a-0022d832cfb0' User entered 'No (N)'	System	01 Apr 2021 21:09:22
	System	01 Apr 2021 21:09:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-01T16:09:12-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'be9ce0a3-95a7-489a-939a-0022d832cfb0' User entered 'No (N)'	System	01 Apr 2021 21:09:22
	System	01 Apr 2021 21:09:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-01T16:09:22-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'be9ce0a3-95a7-489a-939a-0022d832cfb0'	System	01 Apr 2021 21:09:22
User entered '01 Apr 2021 16:09:22'	System	01 Apr 2021 21:09:22

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-04-09T09:21:47-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c1240420-33d1-4670-926e-d8463ead192b'	System	09 Apr 2021 14:22:08
User entered 'No (N)'	System	09 Apr 2021 14:22:08

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-04-09T09:21:52-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c1240420-33d1-4670-926e-d8463ead192b'	System	09 Apr 2021 14:22:08
User entered 'No (N)'	System	09 Apr 2021 14:22:08

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-09T09:21:59-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'c1240420-33d1-4670-926e-d8463ead192b'	System	09 Apr 2021 14:22:08
User entered '09 Apr 2021 09:21:59'	System	09 Apr 2021 14:22:08

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-04-14T18:34:11-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e1f911b3-1b82-40e8-bf49-252b84747bc1' User entered 'No (N)'	System	14 Apr 2021 23:34:24
	System	14 Apr 2021 23:34:24

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-04-14T18:34:15-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e1f911b3-1b82-40e8-bf49-252b84747bc1' User entered 'No (N)'	System	14 Apr 2021 23:34:24
	System	14 Apr 2021 23:34:24

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-14T18:34:18-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e1f911b3-1b82-40e8-bf49-252b84747bc1'	System	14 Apr 2021 23:34:24
User entered '14 Apr 2021 18:34:18'	System	14 Apr 2021 23:34:24

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-04-21T11:12:11-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0f564599-9d1f-4767-b987-702956e80ac3'	System	21 Apr 2021 16:14:46
User entered 'No (N)'	System	21 Apr 2021 16:14:46

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-04-21T11:12:26-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0f564599-9d1f-4767-b987-702956e80ac3'	System	21 Apr 2021 16:14:46
User entered 'No (N)'	System	21 Apr 2021 16:14:46

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-21T11:12:40-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '0f564599-9d1f-4767-b987-702956e80ac3'	System	21 Apr 2021 16:14:46
User entered '21 Apr 2021 11:12:40'	System	21 Apr 2021 16:14:46

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[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 (017ba1e12d48724a)', Time: '2021-04-28T15:50:30-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e96812da-189f-4da4-8a44-0d9219180fe4' User entered 'No (N)'	System	28 Apr 2021 20:50:38
	System	28 Apr 2021 20:50:38

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

Have you been exposed to someone with 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 (017ba1e12d48724a)', Time: '2021-04-28T15:50:33-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e96812da-189f-4da4-8a44-0d9219180fe4'	System	28 Apr 2021 20:50:38
User entered 'No (N)'	System	28 Apr 2021 20:50:38

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-04-28T15:50:38-05:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: 'e96812da-189f-4da4-8a44-0d9219180fe4'	System	28 Apr 2021 20:50:38
User entered '28 Apr 2021 15:50:38'	System	28 Apr 2021 20:50:38

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '02 Nov 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '06 Nov 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '09 Nov 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '13 Nov 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '16 Nov 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '20 Nov 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '23 Nov 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '27 Nov 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '30 Nov 2022 00:01'	System	20 Nov 2020 10:03:30

US3322388

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:17:09

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:03:30
Amendment Manager: User entered '04 Dec 2022 23:59'	System	20 Nov 2020 10:03:30

US3322388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:17:09

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)	25 Apr 2021 19:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-01T17:40:40-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2aeb11c5-c844-4bca-8e49-660bdc641fd0'	System	01 Mar 2021 23:41:39
User entered 'Yes (Y)'	System	01 Mar 2021 23:41:39

US3322388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:17:09

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-01T17:41:18-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2aeb11c5-c844-4bca-8e49-660bdc641fd0'	System	01 Mar 2021 23:41:39
User entered 'No (N)'	System	01 Mar 2021 23:41:39

US3322388

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:17:09

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:42:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (017ba1e12d48724a)', Time: '2021-03-01T17:41:25-06:00', User OID: 'PatientReportedOutcome (US3322388)', ODM File OID: '2aeb11c5-c844-4bca-8e49-660bdc641fd0'	System	01 Mar 2021 23:41:39
User entered '01 Mar 2021 17:41:25'	System	01 Mar 2021 23:41:39

US3322388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Dec 2020 22:14:35

US3322388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '18 Dec 2020'	Elisa Moralez (b) (4)	21 Dec 2020 22:14:35

US3322388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	21 Dec 2020 22:14:35

US3322388

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	21 Dec 2020 22:14:35

US3322388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Dec 2020 22:14:40

US3322388

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 04:24:05
User entered 'I'	System	21 Dec 2020 22:14:40

US3322388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Jan 2021 20:11:59

US3322388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '21 Jan 2021'	Elisa Moralez (b) (4)	26 Jan 2021 20:11:59

US3322388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	26 Jan 2021 20:11:59

US3322388

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	26 Jan 2021 20:11:59

US3322388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	26 Jan 2021 20:12:03

US3322388

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User entered 'I'	System	26 Jan 2021 20:12:03

US3322388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 20:00:20

US3322388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '20 Feb 2021'	Elisa Moralez (b) (4)	21 Feb 2021 20:00:20

US3322388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	21 Feb 2021 20:00:20

US3322388

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Elisa Moralez (b) (4)	21 Feb 2021 20:00:20

US3322388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	21 Feb 2021 19:59:56

US3322388

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User entered 'I'	System	21 Feb 2021 19:59:56

US3322388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Mar 2021 19:03:41

US3322388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '22 Mar 2021'	Elisa Moralez (b) (4)	24 Mar 2021 19:03:41

US3322388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	24 Mar 2021 19:03:41

US3322388

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	24 Mar 2021 19:03:41

US3322388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	24 Mar 2021 19:03:36

US3322388

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:45:38
User entered 'I'	System	24 Mar 2021 19:03:36

US3322388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered 'Yes (Y)'	Elisa Morales (b) (4)	12 Apr 2021 17:57:41
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '12 Apr 2021'	Elisa Morales (b) (4)	12 Apr 2021 17:57:41
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Clinic (Clinic)'	(b) (4) Elisa Morales (b) (4) (b) (4)	12 Apr 2021 17:57:41

US3322388

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 17:57:41

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered '12 Apr 2021'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '11:29'	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:29'	System	12 Apr 2021 17:58:01

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '97.7' F	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered 'Oral (Oral)'	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '76'	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 17:58:01

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '16'	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 17:58:01

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered '140'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 17:58:01

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '89'	Elisa Morales (b) (4)	12 Apr 2021 17:58:01
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 17:58:01

US3322388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered 'No (N)'	Elisa Morales (b) (4)	12 Apr 2021 17:58:09
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	12 Apr 2021 17:58:09
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:18
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered '12 Apr 2021'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:18
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
	(b) (4)	
User entered '11:44'	Elisa Morales (b) (4)	12 Apr 2021 17:58:18
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:44'	System	12 Apr 2021 17:58:18

US3322388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	12 Apr 2021 17:58:24
	(b) (4)	

US3322388

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 17:58:24

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:09
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:15:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:09
User entered '22:09'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:15:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:15
User entered '21 Dec 2020 22:09'	System	23 Dec 2020 16:15:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:09
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:15:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:09
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:15:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '14 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '15 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '16 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '17 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '18 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '19 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 7 (Day 7)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '20 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 8 (Day 8)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '100' F	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 9 (Day 9)'	Elisa Moralez (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '22 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '93'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '102' F	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:01

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 10 (Day 10)'	Frances Saubon (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '23 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '94'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97.8' F	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:11:22

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 11 (Day 11)'	Frances Saubon (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '24 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '94'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '98' F	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:12:50

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 12 (Day 12)'	Frances Saubon (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '25 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '94'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '99.2' F	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:14:04

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 13 (Day 13)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '26 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '94'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '100.4' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Not Done (Not Done)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Not Done (Not Done)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Not Done (Not Done)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Not Done (Not Done)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 14 (Day 14)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '27 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '94'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '99.1' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 15 (Day 15)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '28 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '96'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97.6' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 16 (Day 16)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '29 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97.6' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 17 (Day 17)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '30 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97.7' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 18 (Day 18)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '31 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User closed query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 21 Dec 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).		21 Apr 2021 18:56:34
Query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 21 Dec 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' answered with 'thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	20 Apr 2021 14:08:39
User opened query 'Per CDM: Please note that there are symptoms that are blank/missing in the Covid-19 Assessment 21 Dec 2020 symptom log on log line 18. Please verify if the missing data is available, otherwise please indicate Not Done as per CCGs accordingly. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 12:41:34
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '98.3' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 12:35:51
DataPoint Un-verified.	Elisa Moralez (b) (4)	20 Apr 2021 14:08:33
Signature has been broken.	(b) (4) Elisa Moralez (b) (4)	20 Apr 2021 14:08:33
User entered 'None (None)' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	20 Apr 2021 14:08:33
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 19 (Day 19)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '1 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '96'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 20 (Day 20)'	Elisa Moralez (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '2 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '97'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '98.1' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:32:31

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 21 (Day 21)'	Elisa Moralez (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '3 Jan 2021'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '98'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User entered '%'	System	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered '98.2' F	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (21)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:16
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:34:38

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered '21 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User closed query 'Per CDM RQ: Thank you for the response. According to CCGs please ensure to add COVID-19 diagnosis on the AE section of the eCRF.' (Site from DM).		31 Dec 2020 07:23:36
Query 'Per CDM RQ: Thank you for the response. According to CCGs please ensure to add COVID-19 diagnosis on the AE section of the eCRF.' answered with 'AE has been added, please see updated log' (Site from DM).	Frances Saubon (b) (4) (b) (4)	30 Dec 2020 23:08:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Dec 2020 17:45:55
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	29 Dec 2020 17:45:28
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	28 Dec 2020 16:49:58
User opened query 'Per CDM RQ: Thank you for the response. According to CCGs please ensure to add COVID-19 diagnosis on the AE section of the eCRF.' (Site from DM).		28 Dec 2020 16:49:55
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'site received a positive test result and will add symptomatic covid-19 as an AE' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:28
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	26 Dec 2020 07:05:21
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered '21 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered 'Nasal Swab (Nasal Swab)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[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)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:31
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:37
User entered '1'	System	29 Dec 2020 17:45:55
User entered '0'	System	29 Dec 2020 17:45:28
User entered '1'	System	26 Dec 2020 07:05:21

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

Did the subject have Heart Rate \geq 125 beats per minute

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:35:31
User closed query 'Please confirm response as an O2 sat of 93% is captured on 22Dec2020. Please clarify. (Site from CRA).		19 Feb 2021 19:34:54
Query 'Please confirm response as an O2 sat of 93% is captured on 22Dec2020. Please clarify.' answered with 'updated, apologies' (Site from CRA).	Elisa Moralez (b) (4)	27 Jan 2021 19:02:40
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	27 Jan 2021 19:01:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	27 Jan 2021 19:01:36
User opened query 'Please confirm response as an O2 sat of 93% is captured on 22Dec2020. Please clarify. (Site from CRA).	(b) (4), (b) (6)	26 Jan 2021 21:50:23
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4)	26 Dec 2020 07:09:17
	(b) (4)	

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:35:34
DataPoint Un-verified.	Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:35:37
DataPoint Un-verified.	Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
User entered '22 Dec 2020' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 19:35:40
DataPoint Un-verified.	Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
User entered '93' reason for change: Data Entry Error	(b) (4) Elisa Moralez (b) (4)	27 Jan 2021 19:02:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Start Date](#)

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 21 Dec 2020

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
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User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

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[Start Date](#)

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US3322388

Folder: Covid-19 Assessment 21 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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[Evidence of Shock Requires
Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Folder: Covid-19 Assessment 21 Dec 2020

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[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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[Date of Assessment](#)

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
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User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:44
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:52:47
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:09:17

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:27
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:01:55

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:27
User entered '11:25'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:01:55

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:41
User entered '30 Nov 2020 11:25'	System	03 Dec 2020 15:01:55

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:27
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:01:55

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:17:09

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:27
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:01:55

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 1 (Day 1)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '23 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 2 (Day 2)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '24 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 3 (Day 3)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '25 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Mild (Mild)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 4 (Day 4)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '26 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 5 (Day 5)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '27 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Moderate (Moderate)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 6 (Day 6)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '28 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

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Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 7 (Day 7)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '29 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 8 (Day 8)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered missing code ND - Not Done.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '97' F	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 9 (Day 9)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '1 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '99'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 10 (Day 10)'	Elisa Moralez (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '2 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '100'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '97.8' F	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:10:53

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Day 11 (Day 11)'	Elisa Moralez (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '03 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '0'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '99'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User entered '%'	System	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered '97.3' F	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'None (None)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:17:09

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:47
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:45
User entered 'Not Done (Not Done)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:33

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 16:20:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 16:20:28
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:20:28
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 15:11:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered 'Nasal Swab (Nasal Swab)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[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)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered 'No (N)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:51:52
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:12

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:17:09

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:26:55
User entered '0'	System	04 Dec 2020 16:20:28

US3322388

Folder: Covid-19 Assessment 30 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:17:09

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:27:03
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
DataPoint Un-verified.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 21:53:40
Signature has been broken.	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 21:53:40
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Elisa Moralez (b) (4)	29 Mar 2021 21:53:40
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Jan 2021 19:52:00
User entered 'No (N)'	Elisa Moralez (b) (4)	04 Dec 2020 16:21:42
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 3 (Day 3)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:51

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:51

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User closed query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the 12-digit tracking number in query response for tracking purpose.' (Site from DM).		26 Feb 2021 11:19:22
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
Query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the 12-digit tracking number in query response for tracking purpose.' answered with '917903374118' (Site from DM).	Elisa Moralez (b) (4)	26 Jan 2021 21:05:03
User opened query 'Per GCL Lab Reconciliation: Re-query: Saliva: Thanks for your response, however, please provide the 12-digit tracking number in query response for tracking purpose.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 07:34:07
User closed query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 02DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).		25 Jan 2021 07:34:07
DataPoint Verified.		12 Jan 2021 19:53:54
Query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 02DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' answered with 'shipped 04-dec-2020 1F640783892' (Site from DM).	Elisa Moralez (b) (4)	11 Jan 2021 16:54:29
User opened query 'Per GCL LAB reconciliation: Saliva: Day 3 sample dated 02DEC2020 is missing in PPD Central lab. Please review if the sample has been shipped to PPD then provide the Accession number and tracking number with shipping date to track the sample in PPD. ' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:37:34
User entered '02 Dec 2020'	Elisa Moralez (b) (4)	03 Dec 2020 15:13:51

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 5 (Day 5)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 7 (Day 7)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 9 (Day 9)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 14 (Day 14)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 21 (Day 21)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User accepted default value 'Day 28 (Day 28)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered 'NA (COVID-19 Negative) (NA)'	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:43
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:54
User entered empty.	Elisa Moralez (b) (4) (b) (4)	04 Dec 2020 16:21:58

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '23 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User closed query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		05 Jan 2021 17:52:21
Query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' answered with 'entered' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:19:20
User entered 'Yes (Y)' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:19:15
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 18:04:28
User opened query 'Per CDM: Please enter this data when it becomes available (or is confirmed to be unavailable). This query will remain open in the meantime. ' (Site from DM).		29 Dec 2020 18:04:26
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:08:25
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Dec 2020 07:07:43
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '25 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Jan 2021 15:19:15
User entered empty.	Frances Saubon (b) (4)	26 Dec 2020 07:07:43
	(b) (4)	

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:19:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 05:56:30
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:08:29
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Dec 2020 07:07:43
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User closed query 'Per GCL LAB reconciliation Requery: Saliva: Day 7 sample date in EDC is 28Dec2020, in PPD central Lab is 27Dec2020 and response confirms the the date as 29Dec2020. . Please confirm the correct date of the sample in the response and then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).		22 Jan 2021 16:16:51
Query 'Per GCL LAB reconciliation Requery: Saliva: Day 7 sample date in EDC is 28Dec2020, in PPD central Lab is 27Dec2020 and response confirms the the date as 29Dec2020. . Please confirm the correct date of the sample in the response and then amend EDC or Preclarus as appropriate. Thank you.' answered with 'date in source is 28-Dec-2020, as stated in date of collection entered in EDC' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	18 Jan 2021 15:17:27
User opened query 'Per GCL LAB reconciliation Requery: Saliva: Day 7 sample date in EDC is 28Dec2020, in PPD central Lab is 27Dec2020 and response confirms the the date as 29Dec2020. . Please confirm the correct date of the sample in the response and then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 05:01:00
User closed query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 28DEC2020 is reported in PPD central lab with 27DEC2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 05:01:00
Query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 28DEC2020 is reported in PPD central lab with 27DEC2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' answered with '29-dec-2020 1F600814112' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	11 Jan 2021 16:55:15

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL LAB reconciliation: Saliva: Day 7 sample dated 28DEC2020 is reported in PPD central lab with 27DEC2020. Please review the Preclarus and confirm the correct date in response. If there is a mismatch, then amend EDC or Preclarus as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 10:38:32
User entered '28 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Jan 2021 15:19:37
User entered empty.	(b) (4) Frances Saubon (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	04 Jan 2021 15:19:51
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 05:56:33
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:08:32
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Dec 2020 07:07:43
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '29 Dec 2020' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Jan 2021 15:19:51
User entered empty.	Frances Saubon (b) (4)	26 Dec 2020 07:07:43
	(b) (4)	

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Jan 2021 15:20:10
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 05:56:36
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	26 Dec 2020 07:08:36
User entered empty.	(b) (4)	
	System	26 Dec 2020 07:07:43
	Frances Saubon (b) (4)	26 Dec 2020 07:07:43
	(b) (4)	

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '03 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Jan 2021 15:20:10
User entered empty.	(b) (4) Frances Saubon (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 11JAN2021 labelled as Illness Visit Day 21 which is missing in EDC. Please confirm if the sample was collected then record the data on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:11:02
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 11JAN2021 labelled as Illness Visit Day 21 which is missing in EDC. Please confirm if the sample was collected then record the data on the Saliva collection form. Thank you.' answered with 'ok' (Site from DM).	Elisa Moralez (b) (4)	18 Feb 2021 21:26:26
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 11JAN2021 labelled as Illness Visit Day 21 which is missing in EDC. Please confirm if the sample was collected then record the data on the Saliva collection form. Thank you.' (Site from DM).	(b) (4)	16 Feb 2021 16:49:34
User accepted default value 'Day 21 (Day 21)'	Frances Saubon (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 21:26:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 05:56:39
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:08:39
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Dec 2020 07:07:43
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '11 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 21:26:13
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 21:26:46
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	31 Dec 2020 05:56:42
Query 'Data is required. Please complete.' answered with 'data not available yet' (Site from System).	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:08:42
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Dec 2020 07:07:43
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:57:28
User entered '18 Jan 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	18 Feb 2021 21:26:46
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:07:43

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:06
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:06
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:19
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:06
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:19
User entered 'SICKD1'	System	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '12:15'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User entered '30 Nov 2020 12:15'	System	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '65' in	Elisa Moralez (b) (4)	03 Dec 2020 15:12:48
DataPoint set to visible.	(b) (4) System	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '175.5' lb	Elisa Moralez (b) (4)	03 Dec 2020 15:12:48
DataPoint set to visible.	(b) (4) System	03 Dec 2020 15:11:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '97' F	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered empty.	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '74'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User entered 'bpm'	System	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '16'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User entered 'breaths/min'	System	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '128'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User entered 'mmHg'	System	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:12
User entered '84'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23
User entered 'mmHg'	System	03 Dec 2020 15:12:48

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:23

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:19
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:28
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:19
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:15

US3322388

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:26
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:33

US3322388

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:53:26
User entered '30 Nov 2020'	Elisa Moralez (b) (4) (b) (4)	03 Dec 2020 15:13:33

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:44:45
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 JAN 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).		16 Feb 2021 08:12:29
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 JAN 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' answered with 'ok' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:45:35
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 18 JAN 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 07:17:07
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:44:45
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:44:45
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '15:00'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Dec 2020 15:00'	System	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '65.5' in	Elisa Moralez (b) (4)	23 Dec 2020 16:22:54
DataPoint set to visible.	(b) (4) System	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '171' lb	Elisa Moralez (b) (4)	23 Dec 2020 16:22:54
DataPoint set to visible.	(b) (4) System	23 Dec 2020 16:22:15

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '100' F	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered 'Oral (Oral)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered empty.	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '86'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '16'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '127'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:13
User entered '83'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Dec 2020 16:22:54

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:25
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:23:03

US3322388

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:25
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:23:03

US3322388

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:32
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:23:19

US3322388

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:45:32
User entered '21 Dec 2020'	Elisa Moralez (b) (4) (b) (4)	23 Dec 2020 16:23:19

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:58
DataPoint Verified.		04 Mar 2021 22:27:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:58
DataPoint Verified.		04 Mar 2021 22:27:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:58
DataPoint Verified.		04 Mar 2021 22:27:59
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Clinic (Clinic)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:52:58
User entered 'SICKD28'	System	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '11:30'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
User entered '18 Jan 2021 11:30'	System	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '65.5' in	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 15:46:56
DataPoint set to visible.	(b) (4) System	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '176' lb	(b) (4) Elisa Moralez (b) (4)	05 Feb 2021 15:46:56
DataPoint set to visible.	(b) (4) System	05 Feb 2021 15:46:06

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '97.2' F	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (Oral)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '76'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
User entered 'bpm'	System	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '16'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
User entered 'breaths/min'	System	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '132'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
User entered 'mmHg'	System	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
DataPoint Verified.		04 Mar 2021 22:28:25
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '88'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02
User entered 'mmHg'	System	05 Feb 2021 15:46:56

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:17:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:02

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:06
DataPoint Verified.		04 Mar 2021 22:28:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:47:03

US3322388

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:06
DataPoint Verified.		04 Mar 2021 22:28:32
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:47:03

US3322388

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:09
DataPoint Verified.		04 Mar 2021 22:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:47:09

US3322388

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:17:09

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 16:53:09
DataPoint Verified.		04 Mar 2021 22:28:41
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '18 Jan 2021'	(b) (4) Elisa Moralez (b) (4) (b) (4)	05 Feb 2021 15:47:09

US3322388

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

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:03

US3322388

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

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:03

US3322388

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

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Clinic (Clinic)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:03

US3322388

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

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 22:14:03

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered '0'	Elisa Moralez (b) (4)	08 Apr 2021 18:53:09
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:24:08

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	(b) (4)	
Query 'Was the participant unblinded is No however, data is present. Please reconcile.' answered by data change (Site from System).	System	04 Mar 2021 22:14:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Mar 2021 22:14:27
User opened query 'Was the participant unblinded is No however, data is present. Please reconcile.' (Site from System).	(b) (4)	
User entered 'No (N)'	System	04 Mar 2021 22:14:23
	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23
	(b) (4)	

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:40:55
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' answered with 'updated, thanks!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:21
User entered 'Amendment 6 or later (Amendment 6 or later)'	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:09
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 12:53:17
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:24:08

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 19:40:59
User closed query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' (Site from DM).		09 Apr 2021 19:40:57
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'Per IRT, subject was unblinded on 24FEB2021.' (Site from System).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:26
Query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' answered with 'updated, thanks!' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:24
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	08 Apr 2021 18:53:09
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:09
User entered '24 Feb 2021' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	08 Apr 2021 18:53:09
User opened query 'Per IRT, subject was unblinded on 24FEB2021. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 11:25:39
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 22:14:23

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Placebo (Placebo)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23

US3322388

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:14:23

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'I'	System	04 Mar 2021 22:14:23

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

Form: Unblinding

Generated On: 11 Aug 2021 22:17:09

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'I'	System	04 Mar 2021 22:14:27
User entered empty.	System	04 Mar 2021 22:14:23

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	04 Mar 2021 22:15:40
DataPoint set to visible.	System	04 Mar 2021 22:14:27

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	04 Mar 2021 22:15:40
DataPoint set to visible.	System	04 Mar 2021 22:14:27

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User accepted default value 'Pre-Dose (PREDOSE)'	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '11:19'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '04 Mar 2021 11:19'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '98.0' F	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '70'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'bpm'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '16'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'breaths/min'	System	04 Mar 2021 22:15:40

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '125'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '78'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered missing code ND - Not Done.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:17:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered empty.	System	04 Mar 2021 22:15:40
DataPoint set to visible.	System	04 Mar 2021 22:14:27

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User accepted default value 'Post-Dose (POSTDOSE)'	Elisa Moralez (b) (4) (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '13:46'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '04 Mar 2021 13:46'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '98.1' F	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Oral (Oral)'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '60'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'bpm'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '16'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'breaths/min'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '141'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '85'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mmHg'	System	04 Mar 2021 22:15:40

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:49

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:15:49

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	04 Mar 2021 22:16:04
Query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' answered by data change (Site from System).	System	04 Mar 2021 22:16:04
User opened query 'Was study treatment given? Is Yes but any of these is missing: Treatment Date, Treatment Time, or Treatment Arm. Please review and reconcile.' (Site from System).	System	04 Mar 2021 22:16:00
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'mRNA-1273'	System	04 Mar 2021 22:16:00
DataPoint set to visible.	System	04 Mar 2021 22:14:27

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '13:06'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '04 Mar 2021 13:06'	System	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	04 Mar 2021 22:16:04
User entered empty.	Elisa Moralez (b) (4)	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'ONCE'	System	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'INTRAMUSCULAR'	System	04 Mar 2021 22:16:00

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:17

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:17

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '12:07'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:17

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:17:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '04 Mar 2021 12:07'	System	04 Mar 2021 22:16:17

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:17:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:25

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:17:09

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '04 Mar 2021'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:25

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:17:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '12:02'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:25

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:17:09

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered '04 Mar 2021 12:02'	System	04 Mar 2021 22:16:25

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	04 Mar 2021 22:16:50

US3322388

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:00:29
User entered 'I'	System	04 Mar 2021 22:16:50

US3322388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Mar 2021 19:39:58

US3322388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '12 Mar 2021'	Elisa Moralez (b) (4)	16 Mar 2021 19:39:58

US3322388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Contact Made (CONTACT MADE)'	Elisa Moralez (b) (4)	16 Mar 2021 19:39:58

US3322388

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	16 Mar 2021 19:39:58

US3322388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Yes (Y)'	Elisa Moralez (b) (4)	16 Mar 2021 19:39:48

US3322388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User entered 'I'	System	16 Mar 2021 19:39:48

US3322388

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:55:14
User entered '1'	System	16 Mar 2021 19:39:48
DataPoint set to visible.	System	16 Mar 2021 19:39:48

US3322388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:03

US3322388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:03

US3322388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:03

US3322388

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:17:09

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	29 Mar 2021 20:45:03

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '11:15'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 11:15'	System	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '66'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '17'	(b) (4) (u) (+), (b) (6)	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '147' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:32
User entered '98'		29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '98' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:32
User entered '66'		29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:45:31

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '12:29'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 12:29'	System	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '62'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '15'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '154'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '96'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:17:09

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	29 Mar 2021 20:46:05

US3322388

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:51
User entered 'No (N)'		29 Mar 2021 20:46:40

US3322388

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:17:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '29 Mar 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:46:51
User entered empty.		29 Mar 2021 20:46:40

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

If No, reason not given

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	29 Mar 2021 20:47:08
DataPoint set to visible.	System	16 Mar 2021 19:39:48

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered '11:53'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '29 Mar 2021 11:53'	System	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
User entered 'ONCE'	System	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:17:09

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	29 Mar 2021 20:47:08

US3322388

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	01 Apr 2021 00:01:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 20:47:13

US3322388

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 20:47:13

US3322388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 20:00:14
	(b) (4)	

US3322388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered '06 Apr 2021'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 20:00:14
	(b) (4)	

US3322388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 20:00:14
	(b) (4)	

US3322388

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:17:09

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered empty.	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 20:00:14
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	23 Apr 2021 16:37:41
User entered 'Yes (Y)'	(b) (4) Elisa Morales (b) (4)	19 Apr 2021 20:00:26
	(b) (4)	

US3322388

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:17:09

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 20:00:26

US3322388

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:17:09

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:37
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:58:06
User entered 'Yes (Y)'	Frances Saubon (b) (4)	08 Dec 2020 18:43:10

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per MM re-query: Thank you for your answer. Please confirm how long symptom lasted and if it lasted more than 48 hours then illness visit should have been arranged but not later than 14 days after symptoms started. Please clarify and if symptoms lasted longer than 48 hours and no illness visit was not arranged, then please consider capturing Protocol Deviation. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Jan 2021 14:47:14
Query 'Per MM re-query: Thank you for your answer. Please confirm how long symptom lasted and if it lasted more than 48 hours then illness visit should have been arranged but not later than 14 days after symptoms started. Please clarify and if symptoms lasted longer than 48 hours and no illness visit was not arranged, then please consider capturing Protocol Deviation. Thank you!' answered with 'can confirm that while there were episodes over the three listed days, it did not last for a full 48 hours' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Jan 2021 15:04:11
User opened query 'Per MM re-query: Thank you for your answer. Please confirm how long symptom lasted and if it lasted more than 48 hours then illness visit should have been arranged but not later than 14 days after symptoms started. Please clarify and if symptoms lasted longer than 48 hours and no illness visit was not arranged, then please consider capturing Protocol Deviation. Thank you!' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:50:53
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 10:50:53

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'subject did not have illness visit within 72 hours of this reported symptom' (Site from DM).	Elisa Moralez (b) (4)	04 Jan 2021 15:36:48
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:10:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:45:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:45:51
Data point term sent to Coder	System	08 Dec 2020 18:45:01
User entered 'Diarrhea'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '29 Sep 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Dec 2020 17:00:44
Query 'Data is required. Please provide.' answered with 'time is unknown per source' (Site from System).	Frances Saubon (b) (4)	08 Dec 2020 18:47:36
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 18:44:59
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User entered empty.	System	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '01 Oct 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	09 Dec 2020 17:00:46
Query 'Data is required. Please provide.' answered with 'time is unknown per source' (Site from System).	Frances Saubon (b) (4)	08 Dec 2020 18:47:39
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Dec 2020 18:44:59
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User entered empty.	System	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Related (RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'None (NONE)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'I'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User entered '0'	System	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15
User entered '0'	System	08 Dec 2020 18:44:59

US3322388

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Rhinoviral infections, PT: Rhinovirus infection, LLT: Rhinovirus infection - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 18:56:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 18:56:07
Data point term sent to Coder	System	08 Dec 2020 18:47:03
User entered 'Human Rhinovirus/Enterovirus Sinusitis'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '20 Nov 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User entered empty.	System	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '03 Dec 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User entered empty.	System	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Applicable (NOT APPLICABLE)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'I'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User entered '0'	System	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16
User entered 'I'	System	08 Dec 2020 18:46:19

US3322388

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:16

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of UPPER AND LOWER BACK PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Feb 2021 17:12:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:59:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Feb 2021 21:59:30
Data point term sent to Coder	System	03 Feb 2021 21:58:52
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of UPPER AND LOWER BACK PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' answered with 'done' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 21:58:51
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 21:58:38
User entered 'generalized MYALGIA' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	03 Feb 2021 21:58:38
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of UPPER AND LOWER BACK PAIN. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Jan 2021 05:18:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 17:30:52
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'patient had illness visit on 30-Nov-2020 and it has already been recorded under proper pages in EDC' (Site from DM).	Elisa Moralez (b) (4)	04 Jan 2021 15:37:27
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	31 Dec 2020 09:10:13
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Dec 2020 18:48:43
Data point term sent to Coder	System	08 Dec 2020 18:48:04
User entered 'Myalgia'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '23 Nov 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User entered empty.	System	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '25 Nov 2020'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User entered empty.	System	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Feb 2021 18:49:35
Query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' answered with 'OK' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 23:29:39
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	10 Feb 2021 23:29:35
User opened query 'Per CDM: Per CCGs, if adverse event started after last dose then Action Taken With Investigational Product should be "Not Applicable". Please confirm and reconcile.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 19:56:14
User entered 'None (NONE)'	Frances Saubon (b) (4) (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'I'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	Frances Saubon (b) (4)	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User entered '0'	System	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21
User entered '0'	System	08 Dec 2020 18:47:12

US3322388

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:46:21

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
Reviewed for Safety.		06 Jan 2021 16:12:37
User entered 'USA-US060-2021-mRNA-1273-P301000005'	System	06 Jan 2021 16:12:32
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 16:12:32
Un-reviewed for Safety.		06 Jan 2021 16:11:23
Reviewed for Safety.		06 Jan 2021 16:10:55
User entered empty.		05 Jan 2021 15:06:19

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:09:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Dec 2020 23:09:22
Data point term sent to Coder	System	30 Dec 2020 23:09:01
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	30 Dec 2020 23:08:06
User entered 'Symptomatic COVID-19' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	30 Dec 2020 23:08:06
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Viral infections NEC, PT: Viral infection, LLT: Viral syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Dec 2020 07:07:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Dec 2020 07:07:21
Data point term sent to Coder	System	26 Dec 2020 07:06:48
User entered 'viral syndrome'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User closed query 'PV Query: Please update 'Is this a confirmed diagnosis of Symptomatic Covid-19' to yes. If not, please clarify.' (Site from Safety).		06 Jan 2021 16:10:06
Query 'PV Query: Please update 'Is this a confirmed diagnosis of Symptomatic Covid-19' to yes. If not, please clarify.' answered with 'entry error' (Site from Safety).	Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 20:45:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	05 Jan 2021 20:45:13
User opened query 'PV Query: Please update 'Is this a confirmed diagnosis of Symptomatic Covid-19' to yes. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:05:27
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '14 Dec 2020'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'No (N)' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	19 Jan 2021 18:03:06
User entered 'Yes (Y)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		20 Jan 2021 21:42:58
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	19 Jan 2021 18:03:14
User entered '02 Jan 2021' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	19 Jan 2021 18:03:06
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:00:13
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		11 Jan 2021 16:00:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Noted, information will be updated once available. Thank you.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	09 Jan 2021 20:59:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 19:43:24
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		06 Jan 2021 16:10:13
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'This is still ongoing per source' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	05 Jan 2021 21:45:38

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6)	05 Jan 2021 15:04:18
	Frances Saubon (b) (4)	26 Dec 2020 07:06:36
	(b) (4)	

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'No (N)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered 'Not Related (NOT RELATED)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User closed query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4)	11 Jan 2021 16:00:50
Query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	09 Jan 2021 21:00:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information	Frances Saubon (b) (4) (b) (4)	09 Jan 2021 21:00:36
User opened query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 19:44:11
User closed query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4)	06 Jan 2021 16:10:24
Comment added 'Clarification: Query noted, data will reflect changes once available.'	Frances Saubon (b) (4) (b) (4)	05 Jan 2021 21:47:03
Comment added 'Clarification: Query noted, data will reflect changes once available.'	Frances Saubon (b) (4) (b) (4)	05 Jan 2021 21:47:03
Query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' answered with 'This is still ongoing per source' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	05 Jan 2021 21:45:41
User opened query 'PV Query: As subject has already received both doses of study drug, please update action taken to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:05:52
User entered 'None (NONE)'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:29
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Un-verified.	Elisa Moralez (b) (4)	25 Feb 2021 20:40:02
User entered '0' reason for change: Data Entry Error	Elisa Moralez (b) (4)	25 Feb 2021 20:40:02
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '1'	Frances Saubon (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:30:27
User closed query 'Per source Conmeds taken for Covid-19 . Please confirm with source and update accordingly.' (Site from CRA).		02 Mar 2021 21:27:58
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
Query 'Per source Conmeds taken for Covid-19 . Please confirm with source and update accordingly.'	(b) (4)	
answered with 'AE entered with no action taken, but conmeds entered in conmed list. Added correctly to EDC, source will hopefully be updated soon' (Site from CRA).	Elisa Moralez (b) (4)	25 Feb 2021 20:40:32
	(b) (4)	
DataPoint Un-verified.	Elisa Moralez (b) (4)	25 Feb 2021 20:40:02
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Elisa Moralez (b) (4)	25 Feb 2021 20:40:02
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:04:22
User opened query 'Per source Conmeds taken for Covid-19 . Please confirm with source and update accordingly.' (Site from CRA).		25 Feb 2021 20:04:02
User entered '0'	Frances Saubon (b) (4)	26 Dec 2020 07:06:36
	(b) (4)	

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User entered '0'	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		20 Jan 2021 21:42:51
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	19 Jan 2021 18:03:20
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Frances Saubon (b) (4) (b) (4)	19 Jan 2021 18:03:06
New Information		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 14:02:06
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Jan 2021 16:00:52
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AE is still ongoing. Information will be updated once available.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	09 Jan 2021 20:59:58
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Jan 2021 19:43:54

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	06 Jan 2021 16:10:29
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'This is still ongoing per source' (Site from Safety).	Frances Saubon (b) (4)	05 Jan 2021 21:45:44
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:04:33
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Frances Saubon (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).		19 Jan 2021 14:01:55
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		19 Jan 2021 14:00:34
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:04:22
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		06 Jan 2021 16:10:33
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Please see concomitant medication log for details.' (Site from Safety).	Frances Saubon (b) (4) (b) (4)	05 Jan 2021 21:44:14
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:04:55
User entered empty.	Frances Saubon (b) (4) (b) (4)	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Dec 2020 07:06:36

US3322388

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Aug 2021 22:17:09

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Dec 2020 07:06:36

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:17:09

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:37
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Per source acetaminophen was taken for Covid-19 starting on 14Dec; 1000mg PRN; Loperamide is also noted in source 4mg once/oral on 14Dec20 with end date of 14Dec20.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 21:30:46
Query 'Per source acetaminophen was taken for Covid-19 starting on 14Dec; 1000mg PRN; Loperamide is also noted in source 4mg once/oral on 14Dec20 with end date of 14Dec20.' answered with 'added, thank you' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:52
User opened query 'Per source acetaminophen was taken for Covid-19 starting on 14Dec; 1000mg PRN; Loperamide is also noted in source 4mg once/oral on 14Dec20 with end date of 14Dec20.' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 20:08:34
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 20:04:29
User entered 'Yes (Y)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:58:03

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:34:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:34:28
Data point term sent to Coder	System	05 Oct 2020 15:59:46
User entered 'Trazodone'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'INSOMNIA'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '300'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2010'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:38
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 15:59:40

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: DIPHENYLMETHANE DERIVATIVES, PRODUCT: HYDROXYZINE HYDROCHLORIDE, PRODUCTSYNONYM: VISTARIL [HYDROXYZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:35:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:35:34
Data point term sent to Coder	System	05 Oct 2020 16:00:48
User entered 'Vistaril (hydroxyzine)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'ANXIETY'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '50'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2015'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:39
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:00:33

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 18:41:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 18:41:50
Data point term sent to Coder	System	26 Jan 2021 18:40:53
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	26 Jan 2021 18:39:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 15:27:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	01 Dec 2020 15:27:48
Data point term sent to Coder	System	01 Dec 2020 15:26:40
Coding entries removed.	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:25:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:02:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:02:32
Data point term sent to Coder	System	05 Oct 2020 16:01:50
User entered 'Tramadol'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Please review if this medication was given for Osteoarthritis of Hips, if yes, please note that start date of this medicine is before the start date of the MH condition-UN UNK 2015. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 18:05:50
Query 'Per DM CLR: Please review if this medication was given for Osteoarthritis of Hips, if yes, please note that start date of this medicine is before the start date of the MH condition-UN UNK 2015. Please review and update as appropriate. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	26 Jan 2021 20:23:11
User entered 'Osteoarthritis' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	26 Jan 2021 18:39:59
User opened query 'Per DM CLR: Please review if this medication was given for Osteoarthritis of Hips, if yes, please note that start date of this medicine is before the start date of the MH condition-UN UNK 2015. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 09:14:35
User closed query 'Per DM CLR: Please update the indication and clarify the type and location of the Pain. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate. ' (Site from DM).		02 Dec 2020 18:32:40
Query 'Per DM CLR: Please update the indication and clarify the type and location of the Pain. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:25:58
User entered 'hip PAIN' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:25:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication and clarify the type and location of the Pain. Review and update eCRF as appropriate and ensure update MHx/ Adverse event eCRF as appropriate. ' (Site from DM). User entered 'PAIN'	(b) (4), (b) (6) (b) (4)	01 Dec 2020 14:03:12
	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '50'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'as needed (PRN)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2015' reason for change: Per	(b) (4)	
Query Resolution	Frances Saubon (b) (4)	26 Jan 2021 20:22:58
User entered 'UN UNK 2012'	(b) (4)	
	Blessing Felix-Okoroji	05 Oct 2020 16:01:13
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:41
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:01:13

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Dec 2020 00:07:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 00:07:59
Data point term sent to Coder	System	02 Dec 2020 15:17:21
Coding entries removed.	Elisa Moralez (b) (4)	02 Dec 2020 15:17:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 17:05:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 17:05:22
Data point term sent to Coder	System	05 Oct 2020 16:02:52
User entered 'cyclobenzaprine'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:35:56
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 15:17:22
User entered 'upper and lower back pain' reason for change: New Information	Elisa Moralez (b) (4) (b) (4)	02 Dec 2020 15:17:17
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with AE or Med History eCRF so there is an appropriate condition recorded. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:04:22
User entered 'MUSCLE RELAXANT'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '5'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'as needed (PRN)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:44
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:02:12

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D 3 - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:30
Data point term sent to Coder	System	05 Oct 2020 16:03:53
User entered 'Vitamin D 3'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:32:53
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:00:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:00:16
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:05:50
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'GENERAL HEALTH'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '1000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Other (OTHER)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:31:25
Query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:53:33
User entered 'unknown' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:53:27
User opened query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:03:18
User entered 'NA'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:46
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:03:02

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:31
Data point term sent to Coder	System	05 Oct 2020 16:03:54
User entered 'Vitamin C'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:33:10
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:00:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:00:34
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:06:15
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'GENERAL HEALTH'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '1000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:49
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:03:52

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 19:13:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 19:13:57
Data point term sent to Coder	System	10 Dec 2020 19:12:37
Coding entries removed.	Frances Saubon (b) (4) (b) (4)	10 Dec 2020 19:11:49
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:05:32
Data point term sent to Coder	System	05 Oct 2020 16:04:57
User entered 'topiramate'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM-CLR RQ: Response Noted, however please review if "Indication" of CM should be changed accordingly to MH. Please review and update CM and corresponding MH crf accordingly else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 16:52:01
Query 'Per CDM-CLR RQ: Response Noted, however please review if "Indication" of CM should be changed accordingly to MH. Please review and update CM and corresponding MH crf accordingly else clarify. ' answered with 'updated' (Site from DM).	Frances Saubon (b) (4) (b) (4)	10 Dec 2020 19:11:54
User entered 'Obesity' reason for change: Per Query Resolution	Frances Saubon (b) (4) (b) (4)	10 Dec 2020 19:11:49
User opened query 'Per CDM-CLR RQ: Response Noted, however please review if "Indication" of CM should be changed accordingly to MH. Please review and update CM and corresponding MH crf accordingly else clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:08:40
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).		09 Dec 2020 08:08:40
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'obesity is in medical history with a start date 6 years earlier than the start of this medication and is listed as ongoing' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:28:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM). User entered 'WEIGHT LOSS'	(b) (4), (b) (6) Blessing Felix-Okoroji (b) (4)	01 Dec 2020 14:08:38 05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '200'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2018'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:53
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:04:43

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:07:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:07:21
Data point term sent to Coder	System	05 Oct 2020 16:07:00
User entered 'Probiotics'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:33:45
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:01:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:01:26
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:09:00
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'GENERAL HEALTH'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '12'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Other (OTHER)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:31:32
Query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:53:59
User entered 'unknown' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:53:54
User opened query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:03:38
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	05 Oct 2020 16:12:32
User entered 'N/A' reason for change: Data Entry Error	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:32
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	05 Oct 2020 16:06:34
User entered empty.	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:54
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:06:34

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS AND FEMALE SEX HORMONES IN COMBINATION, ATC: ANDROGENS AND ESTROGENS, PRODUCT: ESTROGENS ESTERIFIED; METHYLTESTOSTERONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	14 Oct 2020 09:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 09:56:23
Data point term sent to Coder	System	05 Oct 2020 16:08:03
User entered 'Estrogens-Methyltestosterone'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:41:00
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' answered with 'it has just been added in source, and will be entered in EDC immediately, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:01:59
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication within this timeframe. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:10:54
User entered 'POSTMENOPAUSE'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0.625/1.25'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2012'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:57
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:07:50

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:12:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:12:31
Data point term sent to Coder	System	05 Oct 2020 16:09:04
User entered 'multivitamin with no iron'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:41:12
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:02:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:30:17
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:11:29
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'general health'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'ONE'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Other (OTHER)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:31:39
Query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:54:19
User entered 'unknown' reason for change: Per Query Resolution	Elisa Moralez (b) (4) (b) (4)	20 Oct 2020 15:54:14
User opened query 'Per CDM -If dose unit is Other, specify 'is recorded as 'NA'. which is unclear. Please select 'Other' from the drop down and mention 'Unknown' in the 'If dose unit is Other, specify' box if the dose is unknown else clarify.. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:03:55
User entered 'NA'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	05 Oct 2020 16:13:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Oct 2020 16:13:01
User entered 'once daily (QD)' reason for change:	Blessing Felix-Okoroji	05 Oct 2020 16:13:01
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Oct 2020 16:08:49
User entered empty.	Blessing Felix-Okoroji	05 Oct 2020 16:08:49
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:59
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:13:01
User entered empty.	System	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:13:01
User entered empty.	System	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:13:01
User entered empty.	System	05 Oct 2020 16:08:49

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, COMBINATIONS WITH VITAMIN D AND/OR OTHER DRUGS, PRODUCT: CALCIUM;MAGNESIUM;ZINC - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:59:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:59:25
Data point term sent to Coder	System	05 Oct 2020 16:11:06
User entered 'calcium -mag- zinc'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:41:22
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:02:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:02:13
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:11:51
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'GENERAL HEALTH'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'ONE PER DAY'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:12
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:10:09

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Oct 2020 16:12:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:12:32
Data point term sent to Coder	System	05 Oct 2020 16:12:10
User entered 'magnesium'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Dec 2020 18:41:33
Query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' answered with 'update' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:02:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 16:02:23
User opened query 'Per DM CLR: Indication for medication is reported as GENERAL HEALTH, however Prophylaxis is indicated as No. Please review and update Prophylaxis as Yes.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 14:12:24
User entered 'No (N)'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'GENERAL HEALTH'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '250'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once daily (QD)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN UNK 2000'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:15
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Oct 2020 16:11:22

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Oct 2020 16:12:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Oct 2020 16:12:31
Data point term sent to Coder	System	05 Oct 2020 16:12:11
User entered 'Famotidine'	Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'ACID REFLUX'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '10'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'as needed (PRN)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'UN Jan 2020'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:17
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Blessing Felix-Okoroji (b) (4)	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Oct 2020 16:12:04

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

Name of Medication

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 23:58:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Dec 2020 23:58:57
Data point term sent to Coder	System	09 Dec 2020 14:12:08
Coding entries removed.	Frances Saubon (b) (4)	09 Dec 2020 14:11:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:22:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 17:22:43
Data point term sent to Coder	System	01 Dec 2020 15:34:50
User entered 'Amoxicillin / Clavulanic acid (Augmentin)'	Elisa Moralez (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Human Rhinovirus/Enterovirus Sinusitis' reason for change: New Information	(b) (4)	
	Frances Saubon (b) (4)	09 Dec 2020 14:11:43
	(b) (4)	
User entered 'Sinus infection'	Elisa Moralez (b) (4)	01 Dec 2020 15:34:07
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '875/125'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'twice daily (BID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '23 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:25
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Dec 2020 15:34:07

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN, PRODUCTSYNONYM: MUCINEX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 20:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 20:35:48
Data point term sent to Coder	System	09 Dec 2020 14:13:08
Data point term sent to Coder	System	01 Dec 2020 15:35:52
User entered 'Guaifenesin (Mucinex)'	Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Human Rhinovirus/Enterovirus Sinusitis' reason for change: Data Entry Error	(b) (4) Frances Saubon (b) (4)	09 Dec 2020 14:12:19
User entered 'Rhinorrhea'	(b) (4) Elisa Moralez (b) (4)	01 Dec 2020 15:35:06
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '1200'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'twice daily (BID)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Elisa Morales (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '23 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '28 Nov 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
DataPoint Un-verified.		02 Mar 2021 21:32:26
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
User entered '2'	System	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
User entered '1'	System	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:46:34
User entered '804 (804)'	System	01 Dec 2020 15:35:06

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM: Please make every effort to provide as much information as possible. Thank you!' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 15:06:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Dec 2020 21:56:54
Data point term sent to Coder	System	21 Dec 2020 15:34:24
Query 'Per CDM: Please make every effort to provide as much information as possible. Thank you!' answered with 'Updated.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 15:33:48
Coding entries removed.		21 Dec 2020 15:33:41
User opened query 'Per CDM: Please make every effort to provide as much information as possible. Thank you!' (Site from DM).		17 Dec 2020 09:47:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 14:15:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 14:15:54
Data point term sent to Coder	System	09 Dec 2020 14:15:21
User entered 'Influenza Vaccine'	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 15:33:41
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).		10 Dec 2020 20:54:09
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	09 Dec 2020 14:15:27
User entered empty.	(b) (4)	
	System	09 Dec 2020 14:14:58
	Frances Saubon (b) (4)	09 Dec 2020 14:14:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'preventative healthcare' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 15:33:41
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).		10 Dec 2020 20:54:11
User opened query 'Data is required. Please complete.' (Site from System).	Frances Saubon (b) (4)	09 Dec 2020 14:15:30
User entered empty.	(b) (4)	
	System	09 Dec 2020 14:14:58
	Frances Saubon (b) (4)	09 Dec 2020 14:14:58
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:33:41
User closed query 'Data is required. Please complete.' (Site from System).		10 Dec 2020 20:54:12
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:15:34
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 14:14:58
User entered empty.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:33:41
User closed query 'Data is required. Please complete.' (Site from System).		10 Dec 2020 20:54:14
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:15:37
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 14:14:58
User entered empty.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'injection' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:33:41
User entered empty.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once (ONCE)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Dec 2020 15:33:41
User closed query 'Data is required. Please complete.' (Site from System).		10 Dec 2020 20:54:15
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:15:40
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 14:14:58
User entered empty.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4)	
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Dec 2020 15:33:41
User closed query 'Data is required. Please		
complete.' (Site from System).		10 Dec 2020 20:54:17
Query 'Data is required. Please complete.' answered	Frances Saubon (b) (4)	09 Dec 2020 14:15:46
with 'data not collected in source' (Site from System).	(b) (4)	
User opened query 'Data is required. Please	System	09 Dec 2020 14:14:58
complete.' (Site from System).		
User entered empty.	Frances Saubon (b) (4)	09 Dec 2020 14:14:58
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '09 Nov 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '09 Nov 2020'	(b) (4) Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
DataPoint Un-verified.		02 Mar 2021 21:32:29
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User closed query 'Per CDM: Please confirm if this "INFLUENZA VACCINE" is taken for a solicited event. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 15:31:47
Query 'Per CDM: Please confirm if this "INFLUENZA VACCINE" is taken for a solicited event. Thank you' answered with 'completed, thank you' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	22 Dec 2020 20:53:54
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	22 Dec 2020 20:53:47
User opened query 'Per CDM: Please confirm if this "INFLUENZA VACCINE" is taken for a solicited event. Thank you' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 18:08:15
User closed query 'Data is required. Please complete.' (Site from System).		10 Dec 2020 20:54:18
Query 'Data is required. Please complete.' answered with 'data not collected in source' (Site from System).	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:15:51
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Dec 2020 14:14:58
User entered empty.	Frances Saubon (b) (4) (b) (4)	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
User entered empty.	System	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
User entered empty.	System	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:04
User entered empty.	System	09 Dec 2020 14:14:58

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	25 Feb 2021 20:54:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 20:54:02
Data point term sent to Coder	System	25 Feb 2021 20:37:43
User entered 'acetaminophen'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Symptomatic COVID-19'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '1000'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'as needed (PRN)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '14 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Mar 2021 17:04:09
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 16:37:14
User closed query 'Please confirm end date as indication notes end date. Thank you.' (Site from CRA).		16 Mar 2021 16:34:24
Query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' answered with 'updated' (Site from DM).	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:14:01
Query 'Please confirm end date as indication notes end date. Thank you.' answered with 'updated' (Site from CRA).	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:13:51
DataPoint Un-verified.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:13:43
Signature has been broken.	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:13:43
User entered 'No (N)' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	15 Mar 2021 19:13:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded for this Con Med as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 04:05:32
DataPoint Verified.		02 Mar 2021 21:32:02
User opened query 'Please confirm end date as indication notes end date. Thank you.' (Site from CRA).		02 Mar 2021 21:31:49
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:09:34
User entered 'Yes (Y)'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:37:12
DataPoint Un-verified.	Elisa Morales (b) (4)	15 Mar 2021 19:13:43
Signature has been broken.	(b) (4) Elisa Morales (b) (4)	15 Mar 2021 19:13:43
User entered '02 Jan 2021' reason for change: Data Entry Error	(b) (4) Elisa Morales (b) (4)	15 Mar 2021 19:13:43
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Morales (b) (4)	25 Feb 2021 20:37:19
	(b) (4)	

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
User entered empty.	System	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
User entered empty.	System	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:11
User entered empty.	System	25 Feb 2021 20:37:19

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: ANTIPROPULSIVES, ATC: ANTIPROPULSIVES, PRODUCT: LOPERAMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:21:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 05:21:47
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4) (b) (4)	26 Feb 2021 04:09:34
Data point term sent to Coder	System	25 Feb 2021 20:38:46
User entered 'loperamide'	Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Symptomatic COVID-19'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '4'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'mg (mg)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'once (ONCE)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'Oral (ORAL)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered empty.	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '14 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '0'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered '14 Dec 2020'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
DataPoint Verified.		02 Mar 2021 21:32:02
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	(b) (4) Elisa Moralez (b) (4) (b) (4)	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
User entered empty.	System	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
User entered empty.	System	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:18
User entered empty.	System	25 Feb 2021 20:37:48

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Mar 2021 19:29:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	23 Mar 2021 19:29:40
Data point term sent to Coder Coding entries removed.	System Elisa Moralez (b) (4)	23 Mar 2021 19:28:54 23 Mar 2021 19:28:45
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Mar 2021 12:07:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	09 Mar 2021 12:07:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 07:53:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 07:53:08
Data point term sent to Coder	System	03 Mar 2021 22:13:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Botox'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'No (N)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 20:01:14
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate.	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:28:48
' answered with 'not a procedure, indication is simply cosmetic per FAQs, now updated, thank you' (Site from DM).		
User entered 'COSMETIC' reason for change: Data Entry Error	Elisa Moralez (b) (4) (b) (4)	23 Mar 2021 19:28:45
User opened query 'Per DM CLR: Please note that there is no ConProc that matches this Con Med indication during this time frame. Please review Con Med use and add the medical procedure in the ConProc eCRF as appropriate.	(b) (4), (b) (6)	21 Mar 2021 02:21:01
' (Site from DM).		
User entered 'Cosmetic procedure'	Elisa Moralez (b) (4) (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'I'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'mL (mL)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'once (ONCE)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Subcutaneous (SUBCUTANEOUS)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '13 Dec 2020'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '0'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'No (N)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '13 Dec 2020'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'No (N)'	Elisa Moralez (b) (4)	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User entered empty.	System	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User entered empty.	System	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Aug 2021 22:17:09

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 23:47:22
User entered empty.	System	03 Mar 2021 22:12:53

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:17:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:32:37
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Signature has been broken.	Elisa Moralez (b) (4)	03 Mar 2021 22:13:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Elisa Moralez (b) (4)	03 Mar 2021 22:13:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
User entered 'No (N)'	Elisa Moralez (b) (4)	20 Feb 2021 19:53:55

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:17:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '23 Nov 2020'	(b) (4) Elisa Morales (b) (4)	03 Mar 2021 22:13:33
	(b) (4)	

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:17:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'COVID-19 nasal swab (negative result)'	(b) (4) Elisa Morales (b) (4)	03 Mar 2021 22:13:33
	(b) (4)	

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4) Elisa Morales (b) (4)	03 Mar 2021 22:13:33
	(b) (4)	

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 11 Aug 2021 22:17:09

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
	(b) (4)	
User entered empty.	Elisa Morales (b) (4)	03 Mar 2021 22:13:33
	(b) (4)	

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:17:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '24 Nov 2020' reason for change: Data Entry Error	System	03 Mar 2021 22:13:51
User opened query 'Future date has been entered. Please correct.' (Site from System).	Elisa Moralez (b) (4)	03 Mar 2021 22:13:51
User entered '24 Nov 2021'	(b) (4)	
	System	03 Mar 2021 22:13:43
	Elisa Moralez (b) (4)	03 Mar 2021 22:13:43
	(b) (4)	

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:17:09

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'COVID-19 nasal swab (negative result)'	Elisa Moralez (b) (4)	03 Mar 2021 22:13:43

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:17:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'Diagnostic (DIAGNOSTIC)'	Elisa Moralez (b) (4)	03 Mar 2021 22:13:43

US3322388

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Aug 2021 22:17:09

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:10:12
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered empty.	Elisa Moralez (b) (4)	03 Mar 2021 22:13:43

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 14:46:14
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:17:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
User entered '06/Jan/2021 16:12'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:17:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'I'		06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 14:46:14
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:17:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
User entered '06/Jan/2021 16:25'	System	06 Jan 2021 16:25:15

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:17:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		11 Jan 2021 16:01:00
User entered 'I'		06 Jan 2021 16:25:15

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 14:46:14
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:17:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
User entered '11/Jan/2021 11:01'	System	11 Jan 2021 16:01:09

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:17:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		20 Jan 2021 21:43:22
User entered 'I'		11 Jan 2021 16:01:09

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:17:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
User entered '20/Jan/2021 16:43'	System	20 Jan 2021 21:43:19

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:17:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		20 Jan 2021 21:43:22
User entered '1'		20 Jan 2021 21:43:19

US3322388

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[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'USA-US060-2021-MRNA-1273-P301000005'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Serious

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Death

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'No (N)'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Veronica'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Teresa'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
Un-reviewed for Safety.	(b) (4)	24 Mar 2021 14:46:14
DataPoint Un-verified.	System	24 Mar 2021 14:46:14
Signature has been broken.	System	24 Mar 2021 14:46:14
User entered 'Fragoso'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Becker'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '6550 Mapleridge Street'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered 'Houston'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'TX'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:12:53
User entered '77081'	System	06 Jan 2021 16:12:32

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	25 Feb 2021 19:58:03
Reviewed for Safety.		06 Jan 2021 16:25:05
User entered 'US'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 22:17:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Mar 2021 14:46:14
User signature succeeded.	Veronica Fragoso (b) (4)	26 Feb 2021 04:09:34
	(b) (4)	
User entered '4'	System	20 Jan 2021 21:43:19
User entered '3'	System	11 Jan 2021 16:01:09
User entered '2'	System	06 Jan 2021 16:25:15
User entered '1'	System	06 Jan 2021 16:12:58

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:17:09

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered '24/Mar/2021 07:46'	(b) (4) System	24 Mar 2021 14:46:14

US3322388

Folder: SAE USA-US060-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:17:09

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 15:12:43
User signature succeeded.	Veronica Fragoso (b) (4)	24 Mar 2021 22:11:31
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Mar 2021 14:46:14