

US3402204 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:28:54

All time stamps listed in this document are displayed in GMT

US3402204

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

[Participant ID](#)

US3402204

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

US3402204

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Date of Birth (MMM yyyy)	(b) (6) 1956
Age	63
Age Units	YEARS
Age (Derived)	63
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 16:59:28

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 16:59:28

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 16:59:28

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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) 15 Feb 2021 16:59:28

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Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	HYPERTENSION
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 (3)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	HYPERLIPIDEMIA
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 (4)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	GOUT - LEFT LEG
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	GASTROESOPHAGEAL REFLUX DISEASE
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 (6)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	ALLERGY TO TREES
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	ALLERGY TO GRASS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Condition	ALLERGY TO CATS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	3 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	10:41 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 10:41
Height (<i>xxx.x</i>)	181.5 cm
Weight (<i>xxx.x</i>)	101.5 kg
BMI (<i>xxx.x</i>)	30.81150 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:59:28

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 16:59:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☐

Specify

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) 15 Feb 2021 16:59:28

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

What was the date of randomization? (dd MMM yyyy) 03 AUG 2020

What was the participant's randomization number? 142673

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

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

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

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

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

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

Liver Disease Yes ☐
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	10:41 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 10:41
Temperature (xxx.x)	97.9 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	3 AUG 2020 12:00
Temperature (xxx.x)	96.9 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)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

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) 3 AUG 2020

What was the treatment time? (00:00-23:59) 11:29 (24 HR)

Treatment Date and Time (derived) 3 AUG 2020 11:29

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	3 AUG 2020
Collection time (00:00-23:59)	11:04 (24 HR)
Collection date and time (derived)	3 AUG 2020 11:04

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Collection date (dd MMM yyyy)			3 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:07	3 AUG 2020 11:07
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

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: 09 Jun 2021 17:28:54

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

96.9 °F

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

Yes ☐
No ☒

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

PC Time Stamp	03 AUG 2020 12:00
PC Open Date & Time	03 AUG 2020 11:49
PC Close Date & Time	03 AUG 2020 14:19

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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 96.2 °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	03 AUG 2020 15:18
PC Open Date & Time	03 AUG 2020 15:14
PC Close Date & Time	04 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

04 AUG 2020 12:25

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 17:06

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

95.4 °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

06 AUG 2020 13:23

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

08 AUG 2020 15:53

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 13:51

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

03 AUG 2020 12:01

PC Open Date & Time

03 AUG 2020 11:49

PC Close Date & Time

03 AUG 2020 14:19

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

03 AUG 2020 15:18

PC Open Date & Time

03 AUG 2020 15:14

PC Close Date & Time

04 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

04 AUG 2020 12:25

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

05 AUG 2020 17:06

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

06 AUG 2020 13:23

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

07 AUG 2020 15:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

08 AUG 2020 15:54

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

09 AUG 2020 13:51

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 12:02
PC Open Date & Time	03 AUG 2020 11:49
PC Close Date & Time	03 AUG 2020 14:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

No ☒

Yes ☐

PC Time stamp	03 AUG 2020 15:19
PC Open Date & Time	03 AUG 2020 15:14
PC Close Date & Time	04 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

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 ☒

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 12:26
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 3548

EAB) (1725)

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 17:06
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

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)

56 of 3548

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 13:23
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

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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US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 15:26
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

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)

60 of 3548

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 15:54
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

EAB) (1725)

62 of 3548

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 13:51
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3402204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

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)	31 AUG 2020
Time of assessment (00:00-23:59)	09:58 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 09:58
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

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)	31 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 10:55
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3402204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

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) 31 AUG 2020

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

Treatment Date and Time (derived) 31 AUG 2020 10:24

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

US3402204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	10:15 (24 HR)
Collection date and time (derived)	31 AUG 2020 10:15

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:14	31 AUG 2020 10:14
Nasopharyngeal Swab 2	No		

US3402204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 10:55

PC Open Date & Time

31 AUG 2020 10:44

PC Close Date & Time

31 AUG 2020 13:14

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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 95.2 °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	31 AUG 2020 22:35
PC Open Date & Time	31 AUG 2020 14:09
PC Close Date & Time	01 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 12:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 12:52

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 14:36

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 14:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

05 SEP 2020 17:56

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

97.8 °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

06 SEP 2020 12:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

31 AUG 2020 10:56

PC Open Date & Time

31 AUG 2020 10:44

PC Close Date & Time

31 AUG 2020 13:14

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

31 AUG 2020 22:35

PC Open Date & Time

31 AUG 2020 14:09

PC Close Date & Time

01 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

01 SEP 2020 12:07

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

02 SEP 2020 12:53

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

03 SEP 2020 14:37

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

04 SEP 2020 14:20

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

05 SEP 2020 17:56

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

06 SEP 2020 12:26

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 10:56
PC Open Date & Time	31 AUG 2020 10:44
PC Close Date & Time	31 AUG 2020 13:14

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 22:36
PC Open Date & Time	31 AUG 2020 14:09
PC Close Date & Time	01 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:08
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 12:54
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

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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US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 14:38
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

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 ☒

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 14:21
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

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EAB) (1725)

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 17:56
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

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 ☒

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:26
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3402204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:28

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

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)	08:34 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 08:34
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

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.

US3402204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 SEP 2020

Collection time (00:00-23:59)

08:49 (24 HR)

Collection date and time (derived)

28 SEP 2020 08:49

US3402204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 16:59:49

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 OCT 2020 12:36:26

Patient Cloud Open Date & Time

03 OCT 2020 00:01

Patient Cloud Close Date & Time

07 OCT 2020 23:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 OCT 2020 09:01:23

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 10:57:21

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 10:25:39

Patient Cloud Open Date & Time

31 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 07:11:20

Patient Cloud Open Date & Time

07 NOV 2020 00:01

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 08:58:27

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 19:34:57

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

25 NOV 2020 06:15:30

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 DEC 2020 12:00:36

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

09 DEC 2020 06:23:20

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 DEC 2020 06:28:46

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 06:33:37

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

30 DEC 2020 12:48:22

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 JAN 2021 06:30:42

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 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)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	False
Congestion	True
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input 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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this 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	14 JAN 2021 16:31:21
Patient Cloud Open Date & Time	13 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 <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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 JAN 2021 16:04:45
Patient Cloud Open Date & Time	20 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
137 of 3548	

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 JAN 2021 18:50:46
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 17:57:29

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

11 FEB 2021 09:51:40

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 06:29:55

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

24 FEB 2021 11:14:36

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

05 MAR 2021 12:03:29

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 20:28:07

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 06:06:07

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 MAR 2021 06:39:14
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 06:52:21

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 06:15:30

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 06:49:26

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 06:30:20

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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="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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	31 OCT 2021 23:59
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US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 <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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 <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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

10 APR 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 691

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

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

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

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

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

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

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 <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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	21 AUG 2022 23:59
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US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Date and time of submission	
Patient Cloud Open Date & Time	21 SEP 2022 00:01
Patient Cloud Close Date & Time	25 SEP 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Date and time of submission

Patient Cloud Open Date & Time	05 OCT 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	09 OCT 2022 23:59
---	-------------------

US3402204

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:28:54

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 12:37:24

US3402204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:20:08

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:20:08

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3402204

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3402204

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

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.

US3402204

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00-23:59)	10:31 (24 HR)
Collection date and time (derived)	2 MAR 2021 10:31

US3402204

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402204

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Date of Contact	11 DEC 2020
Time of Contact	14:00
Date and Time of Contact (derived)	11 DEC 2020 14:00
Type of Contact	<div>Clinic Visit - Scheduled <input type="checkbox"/></div> <div>Clinical Visit - Unscheduled <input checked="" type="checkbox"/></div> <div>Safety Call <input type="checkbox"/></div> <div>Convalescent Tele-visit <input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes <input checked="" type="checkbox"/></div> <div>No <input type="checkbox"/></div>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

Date	06 JAN 2021
------	-------------

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	08 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:47:51

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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)

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Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	09 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (4)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

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

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Form: Symptom Log (5)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.3 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

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Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (6)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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 (7)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (7)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	99.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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 (8)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.4 F
-------------	--------

Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input 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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EAB) (1725)

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Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.5 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input 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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EAB) (1725)

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Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	98.7 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input 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 checked="" type="checkbox"/>
	Moderate	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (12)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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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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Symptom Day

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

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 JAN 2021	
Assessment Not Done	False	
O2 Saturation	90 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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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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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) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	96.6 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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

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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 (15)

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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)

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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	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	94 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (15)

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

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Form: Symptom Log (16)

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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) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021
------	-------------

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

O2 Saturation	88 %
---------------	------

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

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

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

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Form: Symptom Log (16)

Data signed: (b) (4) 26 Apr 2021 22:47:51

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	96.7 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 type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021
------	-------------

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

O2 Saturation	92 %
---------------	------

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

Temperature	97.2 F
-------------	--------

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

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

Shortness of Breath	None <input 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 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (18)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
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 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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Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (19)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 (20)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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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Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
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 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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Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (20)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (21)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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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Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (23)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	97.2 F
-------------	--------

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

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

Shortness of Breath	None	<input 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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Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (24)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	96 %	
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 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 11 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (25)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 JAN 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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"/>

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input checked="" 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 11 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	96.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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EAB) (1725)		

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (27)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	98 %	
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 11 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 (29)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input checked="" 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 11 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 FEB 2021	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input 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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EAB) (1725)		

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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	4 FEB 2021
------	------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

Shortness of Breath	None <input 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (30)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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	5 FEB 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 11 Dec 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (32)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	6 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	96.5 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (33)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input 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 11 Dec 2020

Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	Day 33	<input checked="" type="radio"/>
	Day 34	<input type="radio"/>
	Day 35	<input type="radio"/>
	Day 36	<input type="radio"/>
	Day 37	<input type="radio"/>
	Day 38	<input type="radio"/>
	Day 39	<input type="radio"/>
	Day 40	<input type="radio"/>
Date	7 FEB 2021	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	962 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 11 Dec 2020

Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

	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 11 Dec 2020

Form: Symptom Log (34)

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

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Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Date of Visit	11 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	11 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:51

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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 11 Dec 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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 11 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 JAN 2021
Day 5	Yes	15 JAN 2021
Day 7	Yes	17 JAN 2021
Day 9	Yes	19 JAN 2021
Day 14	Yes	24 JAN 2021
Day 21	Yes	31 JAN 2021
Day 28	Yes	08 FEB 2021

US3402204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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	SICKD1

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Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 JAN 2021
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 JAN 2021 14:10
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 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)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 JAN 2021

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

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Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 JAN 2021

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Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 FEB 2021
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	8 FEB 2021 10:36
Height (xxx.x)	181.5 cm
Weight (xxx.x)	30.8 kg
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 FEB 2021

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

US3402204

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Apr 2021 22:47:51

Generated On: 09 Jun 2021 17:28:54

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 FEB 2021

US3402204

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

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

Visit date (dd MMM yyyy)	2 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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US3402204

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	02 MAR 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 type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	

US3402204

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

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

Collection date (dd MMM yyyy)	2 MAR 2021
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Collection time (00:00-23:59)	10:31 (24 HR)
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Collection date and time (derived)	2 MAR 2021 10:31
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US3402204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00 - 23:59)	10:19
Collection Date and Time (derived)	2 MAR 2021 10:19

US3402204

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:39:14

Generated On: 09 Jun 2021 17:28:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3402204

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

AEID	USA-US059-2021-MRNA-1273-P30 1000004
Adverse event	COVID-19
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	06 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	06 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

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)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

AEID	USA-US059-2021-MRNA-1273-P30 1000007
Adverse event	ACUTE INFECTIVE PERICARDITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	31 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 22:47:50

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

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

SUBJECT SUFFERED WHAT HE
DEEMED SEVER CHEST PAIN
WHILE DRIVING. SUBJECT
WENT TO WALKING WHERE
THEY DID AN ECG COMPLETED
30JAN2021 AND SENT THE
SUBJECT TO THE EMERGENCY
ROOM. SUBJECT WAS GIVEN
NITRO, AND ASPIRIN. SUBJECT
WAS EVALUATED BY
CARDIOLOGY AND WAS SENT
FOR A CARDIAC
CATHERIZATION COMPLETED
30JAN2021. THE CATH SHOWED
NO HEART MUSCLE DAMAGE.
HE WAS DIAGNOSED WITH
ACUTE PERICARDITIS. SUBJECT
WAS DISCHARGED HOME ON
COLCHICINE 0.6MG PO DAILY,
AND NAPROXEN 500MG PO BID.
SUBJECT WAS ALREADY
KNOWN TO BE COVID
POSITIVE. NO COVID TESTING
WAS PERFORMED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:30:57

Generated On: 09 Jun 2021 17:28:54

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

Yes ☒

No ☐

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

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

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) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication ASPIRN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 (3)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 1990
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication NEXIUM

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)	UN UNK 1995	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PRAVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 1990
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) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication QVAR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 80

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) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 22:47:50

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Name of Medication SINGULAIR

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

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 (7)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication SYMBICORT (BUDESONIDE
AND FORMOTEROL)

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 160/4.5

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2005
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication XANX

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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 (9)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
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 (10)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication MEDICAL MARIJUANA

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 3

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 (10)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☐
No ☒

Indication FLU PREVENTION

Dose per administration 0.5

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 (11)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		19 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		19 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication DEXAMETHAZONE

Prophylaxis Yes ☐
No ☒

Indication SARS COVID19

Dose per administration 6

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) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SARS COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		06 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication MONOCLONAL ANTIBODIES

Prophylaxis Yes ☐
No ☒

Indication SARS COVID 19

Dose per administration 700

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 (14)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 checked="" 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)		19 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication CLARITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication SARS COVID 19

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)	11 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 JAN 2021		
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication PREVENT PULMONARY EMBOLISM

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intraocular	<input type="radio"/>
	Intramuscular	<input 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)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
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 (18)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE INFECTIVE
PERICARDITIS

Dose per administration 0.6

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 (18)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 22:47:50

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Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 JAN 2021
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"/>

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication NITRO GLYCERIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)	21 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 35

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 (22)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input 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)	29 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
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 (24)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)	1 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	3 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input 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)	4 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 FEB 2021	
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 (26)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication COATED ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication COVID

Dose per administration 325

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 (26)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		3 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	09 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

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 (29)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)	10 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID

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 (30)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

Name of Medication COLCHICINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE PERICARDITIS

Dose per administration 0.12

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)

534 of 3548

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 22:47:50

Generated On: 09 Jun 2021 17:28:54

	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)		01 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:30:57

Generated On: 09 Jun 2021 17:28:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 23:30:57

Generated On: 09 Jun 2021 17:28:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	CHEST XRAY	Diagnostic	
30 JAN 2021	ECG	Adverse Event	
30 JAN 2021	CARDIAC CATHETERIZATION	Adverse Event	

US3402204

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:28:54

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

US3402204

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:28:54

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 ☐

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000004
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000004
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/JAN/2021 20:44
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000004
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	08/FEB/2021 17:07
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000004
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:44
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000004
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/MAR/2021 12:44
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/FEB/2021 13:46
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/FEB/2021 11:29
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/MAR/2021 08:39
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

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:47:53

Generated On: 09 Jun 2021 17:28:54

SAEID	USA-US059-2021-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input 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 checked="" type="radio"/> No <input 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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/APR/2021 14:17
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

US3402204 (Prod: Meridian Clinical Research, LLC)

US3402204

Form: Participant Creation

Generated On: 09 Jun 2021 17:28:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'US3402204'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:30

US3402204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:34:50

US3402204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:31

US3402204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:34:50

US3402204

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'SCRN'	System	03 Aug 2020 15:34:50

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered (b) (6) 1956'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:32

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '63'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'YEARS'	System	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '63'	System	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Male (M)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'I'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:28:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:38:55

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Aug 2020'	System	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2020'	System	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Amendment 1 (1)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Jennifer Molstead (b) (4)	03 Aug 2020 15:35:04

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:31

US3402204

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:28:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'I'	System	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:28:54

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:28:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:40:02

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:42:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:42:16
Data point term sent to Coder	System	03 Aug 2020 19:41:02
User entered 'asthma'	Traci Hull (b) (4)	03 Aug 2020 19:40:35
	(b) (4)	

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2005'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2005'	System	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2005'	System	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:40:35

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:43:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:43:03
Data point term sent to Coder	System	03 Aug 2020 19:42:04
User entered 'hypertension'	Traci Hull (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 1990'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 1990'	System	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '1990'	System	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:08

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	03 Aug 2020 19:43:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:43:03
Data point term sent to Coder	System	03 Aug 2020 19:42:04
User entered 'hyperlipidemia'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 1990'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 1990'	System	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '1990'	System	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:25

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 11:03:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 11:03:02
Data point term sent to Coder	System	03 Aug 2020 22:24:19
Coding entries removed.	Traci Hull (b) (4)	03 Aug 2020 22:23:49
User entered 'GOUT - left leg' reason for change:	(b) (4)	
Data Entry Error	Traci Hull (b) (4)	03 Aug 2020 22:23:49
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:43:03
Data point term sent to Coder	System	03 Aug 2020 19:42:04
User entered 'gout'	Traci Hull (b) (4)	03 Aug 2020 19:41:54
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 1986'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 1986'	System	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '1986'	System	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:41:54

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
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: Gastroesophageal reflux disease - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	03 Aug 2020 19:44:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:44:04
Data point term sent to Coder	System	03 Aug 2020 19:43:05
User entered 'gastroesophageal reflux disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 1990'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 1990'	System	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '1990'	System	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:42:19

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Post herpetic neuralgia, LLT: Post herpetic neuralgia - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:45:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:45:07
Data point term sent to Coder	System	03 Aug 2020 19:44:06
User entered 'Postherpetic neuralgia'	Traci Hull (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2019'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2019'	System	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2019'	System	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:15

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
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: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:45:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:45:07
Data point term sent to Coder	System	03 Aug 2020 19:44:06
User entered 'chronic neck pain'	Traci Hull (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2019'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2019'	System	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2019'	System	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:36

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	03 Aug 2020 19:45:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:45:07
Data point term sent to Coder	System	03 Aug 2020 19:44:06
User entered 'anxiety'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 1986'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 1986'	System	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '1986'	System	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:43:50

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to plants, LLT: Allergy to plants - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 20:34:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 20:34:05
Data point term sent to Coder	System	03 Aug 2020 19:45:07
User entered 'allergy to trees'	Traci Hull (b) (4)	03 Aug 2020 19:44:16
	(b) (4)	

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2005'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2005'	System	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2005'	System	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:44:16

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Grass allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 19:46:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Aug 2020 19:46:08
Data point term sent to Coder	System	03 Aug 2020 19:45:06
User entered 'allergy to grass'	Traci Hull (b) (4)	03 Aug 2020 19:44:33
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2005'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2005'	System	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2005'	System	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:44:33

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergic to cats - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	03 Aug 2020 19:47:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:47:09
Data point term sent to Coder	System	03 Aug 2020 19:46:07
User entered 'allergy to cats'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'un UNK 2005'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'Jan 2005'	System	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '2005'	System	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:28:54

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered empty.	System	03 Aug 2020 19:45:20

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10:41'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered '3 Aug 2020 10:41'	System	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '181.5' cm	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:46:43
DataPoint set to visible.	(b) (4) System	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '101.5' kg	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:46:43
DataPoint set to visible.	(b) (4) System	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
Amendment Manager: User entered '30.81150'	System	16 Sep 2020 23:41:04
User entered '30.8'	System	03 Aug 2020 19:46:43
DataPoint set to visible.	System	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'kg/m2'	System	03 Aug 2020 19:46:43
DataPoint set to visible.	System	03 Aug 2020 15:35:11

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:14
User entered '97.9' F	Tammy Kohn (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty; reason for change Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	20 Dec 2020 16:28:14
	(b) (4)	
User entered 'Oral (Oral)'	Traci Hull (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:14
User entered '70'	Tammy Kohn (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'bpm'	System	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:14
User entered '14'	Tammy Kohn (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'breaths/min'	System	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:14
User entered '109'	Tammy Kohn (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'mmHg'	System	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:14
User entered '73'	Tammy Kohn (b) (4)	03 Aug 2020 19:46:43
	(b) (4)	

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User entered 'mmHg'	System	03 Aug 2020 19:46:43

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41

US3402204

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41

US3402204

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:47:08

US3402204

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:39:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	31 Aug 2020 14:44:58
User entered '3 Aug 2020'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:47:08

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

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 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'I'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:28:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 17:53:41
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:39:24

US3402204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 19:47:30

US3402204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:47:30

US3402204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	03 Aug 2020 19:47:30

US3402204

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'VISIT1'	System	03 Aug 2020 19:47:30

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '03 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:36

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:43:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:43:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	03 Aug 2020 14:54:36
User entered '142673' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:36

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	03 Aug 2020 14:54:36

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 19:47:46

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:47:46

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:47:46

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:47:46

US3402204

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:28:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:47:46

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '181.5' cm	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '101.5' kg	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '181.5' cm	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '101.5' kg	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10:41'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '3 Aug 2020 10:41'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '97.9' F	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '70'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'bpm'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '14'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'breaths/min'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '109'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '73'	Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '181.5' cm	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:28:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:28:33
User entered '101.5' kg	Tammy Kohn (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 14:04:42
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 minutes' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:38
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		03 Aug 2020 19:50:27
User entered '12:00'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '3 Aug 2020 12:00'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '96.9' F	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '61'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'bpm'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '14'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'breaths/min'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '125'	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 19:50:27
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '86'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	03 Aug 2020 19:50:27

US3402204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 19:50:56
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	Traci Hull (b) (4)	03 Aug 2020 19:50:56

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'MRNA-1273 OR PLACEBO'	System	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '11:29'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '3 Aug 2020 11:29'	System	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'ONCE'	System	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'INTRAMUSCULAR'	System	03 Aug 2020 15:35:49

US3402204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	03 Aug 2020 19:51:20

US3402204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:51:20

US3402204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '11:04'	(b) (4)	
	Traci Hull (b) (4)	03 Aug 2020 19:51:20
	(b) (4)	

US3402204

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '3 Aug 2020 11:04'	System	03 Aug 2020 19:51:20

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '3 Aug 2020'	Traci Hull (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '11:07'	Traci Hull (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '3 Aug 2020 11:07'	System	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered empty.	System	03 Aug 2020 19:51:46

US3402204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 19:52:04

US3402204

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	03 Aug 2020 19:52:04

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:00:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dc8c7c64-46fd-434d-8ffc-b9103566391f' User entered 'Yes (Y)'	System	03 Aug 2020 16:00:48
	System	03 Aug 2020 16:00:48

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:00:33', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dc8c7c64-46fd-434d-8ffc-b9103566391f' User entered '96.9'	System	03 Aug 2020 16:00:48
	System	03 Aug 2020 16:00:48

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:00:39', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dc8c7c64-46fd-434d-8ffc-b9103566391f' User entered 'No (N)'	System	03 Aug 2020 16:00:48
	System	03 Aug 2020 16:00:48

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:00:45', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dc8c7c64-46fd-434d-8ffc-b9103566391f' User entered '03 Aug 2020 12:00'	System	03 Aug 2020 16:00:48
	System	03 Aug 2020 16:00:48

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 11:49'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 14:19'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:17:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b0620510-5933-453d-ab20-14975ab4cd63'	System	03 Aug 2020 19:18:40
User entered 'Yes (Y)'	System	03 Aug 2020 19:18:40

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b0620510-5933-453d-ab20-14975ab4cd63'	System	03 Aug 2020 19:18:40
User entered '96.2'	System	03 Aug 2020 19:18:40

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b0620510-5933-453d-ab20-14975ab4cd63'	System	03 Aug 2020 19:18:40
User entered 'No (N)'	System	03 Aug 2020 19:18:40

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b0620510-5933-453d-ab20-14975ab4cd63'	System	03 Aug 2020 19:18:40
User entered '03 Aug 2020 15:18'	System	03 Aug 2020 19:18:40

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 15:14'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 2'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:23:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1eff68cd-a628-4780-b3ec-6ac7f96a46cd' User entered 'Yes (Y)'	System	04 Aug 2020 16:25:30
	System	04 Aug 2020 16:25:30

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1eff68cd-a628-4780-b3ec-6ac7f96a46cd' User entered '97.5'	System	04 Aug 2020 16:25:30
	System	04 Aug 2020 16:25:30

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1eff68cd-a628-4780-b3ec-6ac7f96a46cd' User entered 'No (N)'	System	04 Aug 2020 16:25:30
	System	04 Aug 2020 16:25:30

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1eff68cd-a628-4780-b3ec-6ac7f96a46cd' User entered '04 Aug 2020 12:25'	System	04 Aug 2020 16:25:30
	System	04 Aug 2020 16:25:30

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 3'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:04', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '50a95765-35c6-4327-ae2b-23941124c350'	System	05 Aug 2020 21:06:20
User entered 'Yes (Y)'	System	05 Aug 2020 21:06:20

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '50a95765-35c6-4327-ae2b-23941124c350' User entered '97.0'	System	05 Aug 2020 21:06:20
	System	05 Aug 2020 21:06:20

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '50a95765-35c6-4327-ae2b-23941124c350'	System	05 Aug 2020 21:06:20
User entered 'No (N)'	System	05 Aug 2020 21:06:20

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '50a95765-35c6-4327-ae2b-23941124c350' User entered '05 Aug 2020 17:06'	System	05 Aug 2020 21:06:20
	System	05 Aug 2020 21:06:20

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 4'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:22:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51c2fabd-6378-48d3-96a8-1f447bf85838' User entered 'Yes (Y)'	System	06 Aug 2020 17:23:21
	System	06 Aug 2020 17:23:21

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:11', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51c2fabd-6378-48d3-96a8-1f447bf85838' User entered '95.4'	System	06 Aug 2020 17:23:21
	System	06 Aug 2020 17:23:21

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51c2fabd-6378-48d3-96a8-1f447bf85838'	System	06 Aug 2020 17:23:21
User entered 'No (N)'	System	06 Aug 2020 17:23:21

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51c2fabd-6378-48d3-96a8-1f447bf85838' User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:23:21
	System	06 Aug 2020 17:23:21

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 5'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:24:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b97194b-3a16-4473-8d79-48e6a6450d00'	System	07 Aug 2020 19:26:13
User entered 'Yes (Y)'	System	07 Aug 2020 19:26:13

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b97194b-3a16-4473-8d79-48e6a6450d00' User entered '96.3'	System	07 Aug 2020 19:26:13
	System	07 Aug 2020 19:26:13

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b97194b-3a16-4473-8d79-48e6a6450d00'	System	07 Aug 2020 19:26:13
User entered 'No (N)'	System	07 Aug 2020 19:26:13

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b97194b-3a16-4473-8d79-48e6a6450d00'	System	07 Aug 2020 19:26:13
User entered '07 Aug 2020 15:26'	System	07 Aug 2020 19:26:13

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 6'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:53:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '605c4030-0d9a-4e04-9059-643e3dffc0f' User entered 'Yes (Y)'	System	08 Aug 2020 19:54:00
	System	08 Aug 2020 19:54:00

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:53:51', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '605c4030-0d9a-4e04-9059-643e3dffcf0f' User entered '97.5'	System	08 Aug 2020 19:54:00
	System	08 Aug 2020 19:54:00

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:53:53', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '605c4030-0d9a-4e04-9059-643e3dffc0f'	System	08 Aug 2020 19:54:00
User entered 'No (N)'	System	08 Aug 2020 19:54:00

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:53:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '605c4030-0d9a-4e04-9059-643e3dffcf0f' User entered '08 Aug 2020 15:53'	System	08 Aug 2020 19:54:00
	System	08 Aug 2020 19:54:00

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 7'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:49:02', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b4502bf1-278b-4176-8686-0aaf3e49f380' User entered 'Yes (Y)'	System	09 Aug 2020 17:51:05
	System	09 Aug 2020 17:51:05

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:50:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b4502bf1-278b-4176-8686-0aaf3e49f380' User entered '96.6'	System	09 Aug 2020 17:51:05
	System	09 Aug 2020 17:51:05

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b4502bf1-278b-4176-8686-0aaf3e49f380' User entered 'No (N)'	System	09 Aug 2020 17:51:05
	System	09 Aug 2020 17:51:05

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b4502bf1-278b-4176-8686-0aaf3e49f380' User entered '09 Aug 2020 13:51'	System	09 Aug 2020 17:51:05
	System	09 Aug 2020 17:51:05

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:04', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b63436ed-b406-418e-ba49-a233e9a7259d'	System	03 Aug 2020 16:01:39
User entered 'None (1)'	System	03 Aug 2020 16:01:39

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b63436ed-b406-418e-ba49-a233e9a7259d' User entered 'No (N)'	System	03 Aug 2020 16:01:39
	System	03 Aug 2020 16:01:39

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b63436ed-b406-418e-ba49-a233e9a7259d' User entered 'No (N)'	System	03 Aug 2020 16:01:39
	System	03 Aug 2020 16:01:39

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b63436ed-b406-418e-ba49-a233e9a7259d'	System	03 Aug 2020 16:01:39
User entered 'None (1)'	System	03 Aug 2020 16:01:39

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:35', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b63436ed-b406-418e-ba49-a233e9a7259d' User entered '03 Aug 2020 12:01'	System	03 Aug 2020 16:01:39
	System	03 Aug 2020 16:01:39

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 11:49'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 14:19'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '47d3384a-8ef9-43a6-a66b-dd841bf9752c' User entered 'None (1)'	System	03 Aug 2020 19:18:57
	System	03 Aug 2020 19:18:57

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '47d3384a-8ef9-43a6-a66b-dd841bf9752c' User entered 'No (N)'	System	03 Aug 2020 19:18:57
	System	03 Aug 2020 19:18:57

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '47d3384a-8ef9-43a6-a66b-dd841bf9752c' User entered 'No (N)'	System	03 Aug 2020 19:18:57
	System	03 Aug 2020 19:18:57

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:53', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '47d3384a-8ef9-43a6-a66b-dd841bf9752c' User entered 'None (1)'	System	03 Aug 2020 19:18:57
	System	03 Aug 2020 19:18:57

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:18:55', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '47d3384a-8ef9-43a6-a66b-dd841bf9752c' User entered '03 Aug 2020 15:18'	System	03 Aug 2020 19:18:57
	System	03 Aug 2020 19:18:57

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 15:14'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 2'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '837ff18e-05e5-446b-8146-cf910fca360b' User entered 'None (1)'	System	04 Aug 2020 16:25:46
	System	04 Aug 2020 16:25:46

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:35', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '837ff18e-05e5-446b-8146-cf910fca360b' User entered 'No (N)'	System	04 Aug 2020 16:25:46
	System	04 Aug 2020 16:25:46

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '837ff18e-05e5-446b-8146-cf910fca360b' User entered 'No (N)'	System	04 Aug 2020 16:25:46
	System	04 Aug 2020 16:25:46

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '837ff18e-05e5-446b-8146-cf910fca360b' User entered 'None (1)'	System	04 Aug 2020 16:25:46
	System	04 Aug 2020 16:25:46

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:44', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '837ff18e-05e5-446b-8146-cf910fca360b' User entered '04 Aug 2020 12:25'	System	04 Aug 2020 16:25:46
	System	04 Aug 2020 16:25:46

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 3'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '282aeff3-e754-4a84-9f24-e28929835d47'	System	05 Aug 2020 21:06:37
User entered 'None (1)'	System	05 Aug 2020 21:06:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '282aeff3-e754-4a84-9f24-e28929835d47'	System	05 Aug 2020 21:06:37
User entered 'No (N)'	System	05 Aug 2020 21:06:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '282aeff3-e754-4a84-9f24-e28929835d47'	System	05 Aug 2020 21:06:37
User entered 'No (N)'	System	05 Aug 2020 21:06:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '282aeff3-e754-4a84-9f24-e28929835d47'	System	05 Aug 2020 21:06:37
User entered 'None (1)'	System	05 Aug 2020 21:06:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '282aeff3-e754-4a84-9f24-e28929835d47'	System	05 Aug 2020 21:06:37
User entered '05 Aug 2020 17:06'	System	05 Aug 2020 21:06:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 4'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '734eb791-43a8-4e7b-9c84-e7164d6e51d8'	System	06 Aug 2020 17:23:37
User entered 'None (1)'	System	06 Aug 2020 17:23:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '734eb791-43a8-4e7b-9c84-e7164d6e51d8' User entered 'No (N)'	System	06 Aug 2020 17:23:37
	System	06 Aug 2020 17:23:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '734eb791-43a8-4e7b-9c84-e7164d6e51d8'	System	06 Aug 2020 17:23:37
User entered 'No (N)'	System	06 Aug 2020 17:23:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '734eb791-43a8-4e7b-9c84-e7164d6e51d8'	System	06 Aug 2020 17:23:37
User entered 'None (1)'	System	06 Aug 2020 17:23:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '734eb791-43a8-4e7b-9c84-e7164d6e51d8' User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:23:37
	System	06 Aug 2020 17:23:37

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 5'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fd84e0ac-3def-45df-af37-77cc22197166'	System	07 Aug 2020 19:26:28
User entered 'None (1)'	System	07 Aug 2020 19:26:28

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fd84e0ac-3def-45df-af37-77cc22197166'	System	07 Aug 2020 19:26:28
User entered 'No (N)'	System	07 Aug 2020 19:26:28

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fd84e0ac-3def-45df-af37-77cc22197166'	System	07 Aug 2020 19:26:28
User entered 'No (N)'	System	07 Aug 2020 19:26:28

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fd84e0ac-3def-45df-af37-77cc22197166'	System	07 Aug 2020 19:26:28
User entered 'None (1)'	System	07 Aug 2020 19:26:28

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fd84e0ac-3def-45df-af37-77cc22197166'	System	07 Aug 2020 19:26:28
User entered '07 Aug 2020 15:26'	System	07 Aug 2020 19:26:28

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 6'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '44fcd5ef-eca6-4b85-98af-2eb464d2badc'	System	08 Aug 2020 19:54:11
User entered 'None (1)'	System	08 Aug 2020 19:54:11

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:02', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '44fcd5ef-eca6-4b85-98af-2eb464d2badc'	System	08 Aug 2020 19:54:11
User entered 'No (N)'	System	08 Aug 2020 19:54:11

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:05', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '44fcd5ef-eca6-4b85-98af-2eb464d2badc'	System	08 Aug 2020 19:54:11
User entered 'No (N)'	System	08 Aug 2020 19:54:11

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:07', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '44fcd5ef-eca6-4b85-98af-2eb464d2badc'	System	08 Aug 2020 19:54:11
User entered 'None (1)'	System	08 Aug 2020 19:54:11

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '44fcd5ef-eca6-4b85-98af-2eb464d2badc' User entered '08 Aug 2020 15:54'	System	08 Aug 2020 19:54:11
	System	08 Aug 2020 19:54:11

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 7'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4f3a8861-63a3-4336-9d08-deb5c214c3c6'	System	09 Aug 2020 17:51:16
User entered 'None (1)'	System	09 Aug 2020 17:51:16

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:08', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4f3a8861-63a3-4336-9d08-deb5c214c3c6'	System	09 Aug 2020 17:51:16
User entered 'No (N)'	System	09 Aug 2020 17:51:16

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4f3a8861-63a3-4336-9d08-deb5c214c3c6' User entered 'No (N)'	System	09 Aug 2020 17:51:16
	System	09 Aug 2020 17:51:16

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:12', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4f3a8861-63a3-4336-9d08-deb5c214c3c6'	System	09 Aug 2020 17:51:16
User entered 'None (1)'	System	09 Aug 2020 17:51:16

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4f3a8861-63a3-4336-9d08-deb5c214c3c6' User entered '09 Aug 2020 13:51'	System	09 Aug 2020 17:51:16
	System	09 Aug 2020 17:51:16

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:41', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:53', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:01:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:02:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:02:04', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:02:07', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'None (0)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:02:12', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered 'No (N)'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T12:02:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'f7232736-9d27-4c6b-b1de-2d9672b533e6' User entered '03 Aug 2020 12:02'	System	03 Aug 2020 16:02:19
	System	03 Aug 2020 16:02:19

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 11:49'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 14:19'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 1, after vaccination (at home)'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:04', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:08', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:11', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered 'None (0)'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112'	System	03 Aug 2020 19:19:22
User entered 'No (N)'	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-03T15:19:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '207e4abc-3a41-4f8e-8fd4-90a2d59dd112' User entered '03 Aug 2020 15:19'	System	03 Aug 2020 19:19:22
	System	03 Aug 2020 19:19:22

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Aug 2020 15:14'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 2'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:48', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:54', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:56', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:25:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered 'None (0)'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:26:05', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968'	System	04 Aug 2020 16:26:08
User entered 'No (N)'	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-04T12:26:07', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd5482b73-a894-4118-b862-0907b125e968' User entered '04 Aug 2020 12:26'	System	04 Aug 2020 16:26:08
	System	04 Aug 2020 16:26:08

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 3'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:39', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:41', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:45', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'None (0)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered 'No (N)'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-05T17:06:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '35358da4-d8e4-48c0-8b68-d064d64145dc' User entered '05 Aug 2020 17:06'	System	05 Aug 2020 21:06:55
	System	05 Aug 2020 21:06:55

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 4'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088' User entered 'None (0)'	System	06 Aug 2020 17:24:00
	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:44', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088' User entered 'None (0)'	System	06 Aug 2020 17:24:00
	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088'	System	06 Aug 2020 17:24:00
User entered 'None (0)'	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088' User entered 'None (0)'	System	06 Aug 2020 17:24:00
	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088' User entered 'None (0)'	System	06 Aug 2020 17:24:00
	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088'	System	06 Aug 2020 17:24:00
User entered 'None (0)'	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:55', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088'	System	06 Aug 2020 17:24:00
User entered 'No (N)'	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-06T13:23:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9845c71c-26e7-4e8e-985e-44fff1b87088' User entered '06 Aug 2020 13:23'	System	06 Aug 2020 17:24:00
	System	06 Aug 2020 17:24:00

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 5'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:42', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'None (0)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered 'No (N)'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-07T15:26:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0d27898d-8e6e-441b-b032-393ea2153af8' User entered '07 Aug 2020 15:26'	System	07 Aug 2020 19:26:51
	System	07 Aug 2020 19:26:51

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 6'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:15', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'None (0)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered 'No (N)'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-08T15:54:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5eec2ce6-7511-48be-b309-e770a12c6316' User entered '08 Aug 2020 15:54'	System	08 Aug 2020 19:54:27
	System	08 Aug 2020 19:54:27

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '08 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 7'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:22', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'None (0)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered 'No (N)'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-09T13:51:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'af13009c-19c9-447e-97ad-c7579c97dcd7' User entered '09 Aug 2020 13:51'	System	09 Aug 2020 17:51:33
	System	09 Aug 2020 17:51:33

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '09 Aug 2020 12:00'	System	03 Aug 2020 15:35:49

US3402204

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '10 Aug 2020 11:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	11 Aug 2020 18:44:43
	(b) (4)	

US3402204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10 Aug 2020'	Traci Hull (b) (4)	11 Aug 2020 18:44:43

US3402204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	11 Aug 2020 18:44:43

US3402204

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Traci Hull (b) (4)	11 Aug 2020 18:44:43

US3402204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	11 Aug 2020 18:44:49

US3402204

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	11 Aug 2020 18:44:49

US3402204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	19 Aug 2020 13:04:18
	(b) (4)	

US3402204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '17 Aug 2020'	Traci Hull (b) (4)	19 Aug 2020 13:04:18

US3402204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	19 Aug 2020 13:04:18

US3402204

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Traci Hull (b) (4)	19 Aug 2020 13:04:18

US3402204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Aug 2020 13:04:27

US3402204

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	19 Aug 2020 13:04:27

US3402204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:42

US3402204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '24 Aug 2020'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:42

US3402204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:42

US3402204

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:42

US3402204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:46

US3402204

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	31 Aug 2020 14:44:46

US3402204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:58

US3402204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '31 Aug 2020'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:58

US3402204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:44:58

US3402204

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'VISIT2'	System	31 Aug 2020 14:44:58

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '31 Aug 2020'	Traci Hull (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '09:58'	Traci Hull (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '31 Aug 2020 09:58'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '97.8' F	(b) (4)	
	Traci Hull (b) (4)	31 Aug 2020 21:24:24
	(b) (4)	

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '62'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'bpm'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'breaths/min'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '109'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '75'	Traci Hull (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '31 Aug 2020'	Traci Hull (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '10:55'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '31 Aug 2020 10:55'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '97.5' F	(b) (4)	
	Traci Hull (b) (4)	31 Aug 2020 21:24:24
	(b) (4)	

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '59'	Traci Hull (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'bpm'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'breaths/min'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '120'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '84'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	31 Aug 2020 21:24:24

US3402204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	31 Aug 2020 21:24:30
	(b) (4)	

US3402204

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '31 Aug 2020'	Traci Hull (b) (4)	31 Aug 2020 21:24:30

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '31 Aug 2020'	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10:24'	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '31 Aug 2020 10:24'	System	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'ONCE'	System	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:28:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 14:45:21

US3402204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:52

US3402204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '31 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:24:52

US3402204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10:15'	(b) (4) Traci Hull (b) (4)	31 Aug 2020 21:24:52

US3402204

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '31 Aug 2020 10:15'	System	31 Aug 2020 21:24:52

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '31 Aug 2020'	Traci Hull (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '10:14'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '31 Aug 2020 10:14'	System	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered empty.	System	31 Aug 2020 21:25:04

US3402204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	31 Aug 2020 21:25:07

US3402204

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	31 Aug 2020 21:25:07

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:55:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '67bc6e21-7954-46d9-afdc-c201590502cb' User entered 'Yes (Y)'	System	31 Aug 2020 15:04:33
	System	31 Aug 2020 15:04:33

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:55:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '67bc6e21-7954-46d9-afdc-c201590502cb' User entered '97.5'	System	31 Aug 2020 15:04:33
	System	31 Aug 2020 15:04:33

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:55:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '67bc6e21-7954-46d9-afdc-c201590502cb' User entered 'No (N)'	System	31 Aug 2020 15:04:33
	System	31 Aug 2020 15:04:33

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:55:51', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '67bc6e21-7954-46d9-afdc-c201590502cb' User entered '31 Aug 2020 10:55'	System	31 Aug 2020 15:04:33
	System	31 Aug 2020 15:04:33

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 10:44'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 13:14'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:32:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'e06847f6-45da-48e5-ae33-15fa1c866a5c' User entered 'Yes (Y)'	System	01 Sep 2020 02:35:36
	System	01 Sep 2020 02:35:36

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'e06847f6-45da-48e5-ae33-15fa1c866a5c' User entered '95.2'	System	01 Sep 2020 02:35:36
	System	01 Sep 2020 02:35:36

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'e06847f6-45da-48e5-ae33-15fa1c866a5c' User entered 'No (N)'	System	01 Sep 2020 02:35:36

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'e06847f6-45da-48e5-ae33-15fa1c866a5c' User entered '31 Aug 2020 22:35'	System	01 Sep 2020 02:35:36
	System	01 Sep 2020 02:35:36

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 14:09'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 2'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dcf6f684-3078-4bc5-bc19-8d59baee77dd' User entered 'Yes (Y)'	System	01 Sep 2020 16:07:31
	System	01 Sep 2020 16:07:31

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dcf6f684-3078-4bc5-bc19-8d59baee77dd' User entered '96.3'	System	01 Sep 2020 16:07:31
	System	01 Sep 2020 16:07:31

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dcf6f684-3078-4bc5-bc19-8d59baee77dd'	System	01 Sep 2020 16:07:31
User entered 'No (N)'	System	01 Sep 2020 16:07:31

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'dcf6f684-3078-4bc5-bc19-8d59baee77dd' User entered '01 Sep 2020 12:07'	System	01 Sep 2020 16:07:31
	System	01 Sep 2020 16:07:31

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 3'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'cd6faa67-b212-4a1a-9d30-86eee35eaf2c' User entered 'Yes (Y)'	System	02 Sep 2020 16:52:45
	System	02 Sep 2020 16:52:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:30', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'cd6faa67-b212-4a1a-9d30-86eee35eaf2c' User entered '96.9'	System	02 Sep 2020 16:52:45
	System	02 Sep 2020 16:52:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'cd6faa67-b212-4a1a-9d30-86eee35eaf2c'	System	02 Sep 2020 16:52:45
User entered 'No (N)'	System	02 Sep 2020 16:52:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'cd6faa67-b212-4a1a-9d30-86eee35eaf2c' User entered '02 Sep 2020 12:52'	System	02 Sep 2020 16:52:45
	System	02 Sep 2020 16:52:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 4'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:36:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '586c7c9a-1c5a-493e-aa5e-b5109426fdd3' User entered 'Yes (Y)'	System	03 Sep 2020 18:36:56
	System	03 Sep 2020 18:36:56

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:36:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '586c7c9a-1c5a-493e-aa5e-b5109426fdd3' User entered '97.0'	System	03 Sep 2020 18:36:56
	System	03 Sep 2020 18:36:56

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:36:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '586c7c9a-1c5a-493e-aa5e-b5109426fdd3'	System	03 Sep 2020 18:36:56
User entered 'No (N)'	System	03 Sep 2020 18:36:56

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:36:51', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '586c7c9a-1c5a-493e-aa5e-b5109426fdd3' User entered '03 Sep 2020 14:36'	System	03 Sep 2020 18:36:56
	System	03 Sep 2020 18:36:56

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 5'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:17:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6e9e0ba6-1b1b-49ff-ae30-176e1be6b768'	System	04 Sep 2020 18:20:45
User entered 'Yes (Y)'	System	04 Sep 2020 18:20:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6e9e0ba6-1b1b-49ff-ae30-176e1be6b768' User entered '96.4'	System	04 Sep 2020 18:20:45
	System	04 Sep 2020 18:20:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6e9e0ba6-1b1b-49ff-ae30-176e1be6b768'	System	04 Sep 2020 18:20:45
User entered 'No (N)'	System	04 Sep 2020 18:20:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6e9e0ba6-1b1b-49ff-ae30-176e1be6b768' User entered '04 Sep 2020 14:20'	System	04 Sep 2020 18:20:45
	System	04 Sep 2020 18:20:45

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 6'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:02', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2f61ff01-f879-4b3a-9d89-70b9ac68ffe1' User entered 'Yes (Y)'	System	05 Sep 2020 21:56:14
	System	05 Sep 2020 21:56:14

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:05', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2f61ff01-f879-4b3a-9d89-70b9ac68ffe1' User entered '97.4'	System	05 Sep 2020 21:56:14
	System	05 Sep 2020 21:56:14

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:07', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2f61ff01-f879-4b3a-9d89-70b9ac68ffe1'	System	05 Sep 2020 21:56:14
User entered 'No (N)'	System	05 Sep 2020 21:56:14

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2f61ff01-f879-4b3a-9d89-70b9ac68ffe1' User entered '05 Sep 2020 17:56'	System	05 Sep 2020 21:56:14
	System	05 Sep 2020 21:56:14

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 7'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1588d9cb-96b8-47f5-879a-563e344f6e33' User entered 'Yes (Y)'	System	06 Sep 2020 16:26:32
	System	06 Sep 2020 16:26:32

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1588d9cb-96b8-47f5-879a-563e344f6e33' User entered '97.8'	System	06 Sep 2020 16:26:32
	System	06 Sep 2020 16:26:32

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1588d9cb-96b8-47f5-879a-563e344f6e33'	System	06 Sep 2020 16:26:32
User entered 'No (N)'	System	06 Sep 2020 16:26:32

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1588d9cb-96b8-47f5-879a-563e344f6e33' User entered '06 Sep 2020 12:26'	System	06 Sep 2020 16:26:32
	System	06 Sep 2020 16:26:32

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:55:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1716c9b8-4b38-45a9-ae06-c12c91ca5831' User entered 'None (1)'	System	31 Aug 2020 15:04:39
	System	31 Aug 2020 15:04:39

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1716c9b8-4b38-45a9-ae06-c12c91ca5831' User entered 'No (N)'	System	31 Aug 2020 15:04:39
	System	31 Aug 2020 15:04:39

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1716c9b8-4b38-45a9-ae06-c12c91ca5831' User entered 'No (N)'	System	31 Aug 2020 15:04:39
	System	31 Aug 2020 15:04:39

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:07', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1716c9b8-4b38-45a9-ae06-c12c91ca5831' User entered 'None (1)'	System	31 Aug 2020 15:04:39
	System	31 Aug 2020 15:04:39

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:09', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1716c9b8-4b38-45a9-ae06-c12c91ca5831' User entered '31 Aug 2020 10:56'	System	31 Aug 2020 15:04:39
	System	31 Aug 2020 15:04:39

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 10:44'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 13:14'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:39', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2a0a9821-234a-4be6-adaa-23715b4429a7'	System	01 Sep 2020 02:35:57
User entered 'None (1)'	System	01 Sep 2020 02:35:57

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2a0a9821-234a-4be6-adaa-23715b4429a7' User entered 'No (N)'	System	01 Sep 2020 02:35:57
	System	01 Sep 2020 02:35:57

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:45', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2a0a9821-234a-4be6-adaa-23715b4429a7' User entered 'No (N)'	System	01 Sep 2020 02:35:57
	System	01 Sep 2020 02:35:57

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2a0a9821-234a-4be6-adaa-23715b4429a7' User entered 'None (1)'	System	01 Sep 2020 02:35:57

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:53', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '2a0a9821-234a-4be6-adaa-23715b4429a7' User entered '31 Aug 2020 22:35'	System	01 Sep 2020 02:35:57
	System	01 Sep 2020 02:35:57

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 14:09'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 2'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:33', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7dd1d8b5-7999-464e-91f1-aef05277850d' User entered 'None (1)'	System	01 Sep 2020 16:07:46
	System	01 Sep 2020 16:07:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:35', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7dd1d8b5-7999-464e-91f1-aef05277850d' User entered 'No (N)'	System	01 Sep 2020 16:07:46
	System	01 Sep 2020 16:07:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7dd1d8b5-7999-464e-91f1-aef05277850d' User entered 'No (N)'	System	01 Sep 2020 16:07:46
	System	01 Sep 2020 16:07:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7dd1d8b5-7999-464e-91f1-aef05277850d' User entered 'None (1)'	System	01 Sep 2020 16:07:46
	System	01 Sep 2020 16:07:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7dd1d8b5-7999-464e-91f1-aef05277850d' User entered '01 Sep 2020 12:07'	System	01 Sep 2020 16:07:46
	System	01 Sep 2020 16:07:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 3'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:48', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4265233e-fec6-4070-b8c2-d510e7b6e557'	System	02 Sep 2020 16:53:09
User entered 'None (1)'	System	02 Sep 2020 16:53:09

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:52:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4265233e-fec6-4070-b8c2-d510e7b6e557'	System	02 Sep 2020 16:53:09
User entered 'No (N)'	System	02 Sep 2020 16:53:09

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4265233e-fec6-4070-b8c2-d510e7b6e557'	System	02 Sep 2020 16:53:09
User entered 'No (N)'	System	02 Sep 2020 16:53:09

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4265233e-fec6-4070-b8c2-d510e7b6e557'	System	02 Sep 2020 16:53:09
User entered 'None (1)'	System	02 Sep 2020 16:53:09

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '4265233e-fec6-4070-b8c2-d510e7b6e557'	System	02 Sep 2020 16:53:09
User entered '02 Sep 2020 12:53'	System	02 Sep 2020 16:53:09

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 4'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ceb506ae-5b70-4066-85ab-106e6ddd392b' User entered 'None (1)'	System	03 Sep 2020 18:37:46
	System	03 Sep 2020 18:37:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:30', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ceb506ae-5b70-4066-85ab-106e6ddd392b' User entered 'No (N)'	System	03 Sep 2020 18:37:46
	System	03 Sep 2020 18:37:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ceb506ae-5b70-4066-85ab-106e6ddd392b' User entered 'No (N)'	System	03 Sep 2020 18:37:46
	System	03 Sep 2020 18:37:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:41', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ceb506ae-5b70-4066-85ab-106e6ddd392b' User entered 'None (1)'	System	03 Sep 2020 18:37:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ceb506ae-5b70-4066-85ab-106e6ddd392b' User entered '03 Sep 2020 14:37'	System	03 Sep 2020 18:37:46
	System	03 Sep 2020 18:37:46

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 5'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '06693ecf-b814-40a4-9b40-06b9770922e6' User entered 'None (1)'	System	04 Sep 2020 18:20:55
	System	04 Sep 2020 18:20:55

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:48', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '06693ecf-b814-40a4-9b40-06b9770922e6' User entered 'No (N)'	System	04 Sep 2020 18:20:55
	System	04 Sep 2020 18:20:55

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '06693ecf-b814-40a4-9b40-06b9770922e6' User entered 'No (N)'	System	04 Sep 2020 18:20:55
	System	04 Sep 2020 18:20:55

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '06693ecf-b814-40a4-9b40-06b9770922e6' User entered 'None (1)'	System	04 Sep 2020 18:20:55
	System	04 Sep 2020 18:20:55

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '06693ecf-b814-40a4-9b40-06b9770922e6' User entered '04 Sep 2020 14:20'	System	04 Sep 2020 18:20:55
	System	04 Sep 2020 18:20:55

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 6'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:12', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e90d7f0-f239-465b-ba41-777425a744b6'	System	05 Sep 2020 21:56:20
User entered 'None (1)'	System	05 Sep 2020 21:56:20

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e90d7f0-f239-465b-ba41-777425a744b6'	System	05 Sep 2020 21:56:20
User entered 'No (N)'	System	05 Sep 2020 21:56:20

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e90d7f0-f239-465b-ba41-777425a744b6' User entered 'No (N)'	System	05 Sep 2020 21:56:20

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e90d7f0-f239-465b-ba41-777425a744b6'	System	05 Sep 2020 21:56:20
User entered 'None (1)'	System	05 Sep 2020 21:56:20

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:19', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e90d7f0-f239-465b-ba41-777425a744b6' User entered '05 Sep 2020 17:56'	System	05 Sep 2020 21:56:20
	System	05 Sep 2020 21:56:20

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 7'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:30', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '39fe8b63-1c31-431d-b8db-9ae9ab17526f' User entered 'None (1)'	System	06 Sep 2020 16:26:40
	System	06 Sep 2020 16:26:40

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '39fe8b63-1c31-431d-b8db-9ae9ab17526f' User entered 'No (N)'	System	06 Sep 2020 16:26:40
	System	06 Sep 2020 16:26:40

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:33', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '39fe8b63-1c31-431d-b8db-9ae9ab17526f' User entered 'No (N)'	System	06 Sep 2020 16:26:40
	System	06 Sep 2020 16:26:40

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '39fe8b63-1c31-431d-b8db-9ae9ab17526f' User entered 'None (1)'	System	06 Sep 2020 16:26:40
	System	06 Sep 2020 16:26:40

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '39fe8b63-1c31-431d-b8db-9ae9ab17526f' User entered '06 Sep 2020 12:26'	System	06 Sep 2020 16:26:40
	System	06 Sep 2020 16:26:40

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:15', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:19', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:22', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'None (0)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered 'No (N)'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T10:56:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '1600e0f8-4ad8-4ee9-9cd9-f589bba7e88a' User entered '31 Aug 2020 10:56'	System	31 Aug 2020 15:04:41
	System	31 Aug 2020 15:04:41

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 10:44'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 13:14'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:35:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:08', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33' User entered 'None (0)'	System	01 Sep 2020 02:36:15
	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:10', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33'	System	01 Sep 2020 02:36:15
User entered 'No (N)'	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-08-31T22:36:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15d72dd1-bb15-4ecf-94cd-3f98b8022e33'	System	01 Sep 2020 02:36:15
User entered '31 Aug 2020 22:36'	System	01 Sep 2020 02:36:15

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '31 Aug 2020 14:09'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 2'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:54', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:56', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'None (0)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:07:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered 'No (N)'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-01T12:08:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ca0cbde0-77f2-4fc5-8f21-3c4b81b98be0' User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:08:05
	System	01 Sep 2020 16:08:05

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 3'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:35', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:53', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:53:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'None (0)'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:54:01', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered 'No (N)'	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-02T12:54:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '49ca2ecf-6c1d-4c7d-b4b1-f5b1e98b640e' User entered '02 Sep 2020 12:54'	System	02 Sep 2020 16:54:07
	System	02 Sep 2020 16:54:07

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 4'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:48', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:51', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:54', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:55', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:37:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'None (0)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:38:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered 'No (N)'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-03T14:38:02', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '832e98ab-4ab5-43d4-8fc9-935aadf2467d' User entered '03 Sep 2020 14:38'	System	03 Sep 2020 18:38:03
	System	03 Sep 2020 18:38:03

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 5'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:56', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47' User entered 'None (0)'	System	04 Sep 2020 18:21:09
	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47'	System	04 Sep 2020 18:21:09
User entered 'None (0)'	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47' User entered 'None (0)'	System	04 Sep 2020 18:21:09
	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:20:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47' User entered 'None (0)'	System	04 Sep 2020 18:21:09
	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:21:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47'	System	04 Sep 2020 18:21:09
User entered 'None (0)'	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:21:02', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47' User entered 'None (0)'	System	04 Sep 2020 18:21:09
	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:21:03', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47'	System	04 Sep 2020 18:21:09
User entered 'No (N)'	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-04T14:21:05', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'b75a7772-e06f-4533-a4c7-5f3a06ff2f47' User entered '04 Sep 2020 14:21'	System	04 Sep 2020 18:21:09
	System	04 Sep 2020 18:21:09

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 6'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:22', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'None (0)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:30', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered 'No (N)'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-05T17:56:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'daa7075e-7584-4994-b6e7-b55c2c5b1a4f' User entered '05 Sep 2020 17:56'	System	05 Sep 2020 21:56:36
	System	05 Sep 2020 21:56:36

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	31 Aug 2020 14:45:21
User entered 'Day 7'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:39', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:41', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:42', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:43', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:45', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'None (0)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:47', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered 'No (N)'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-09-06T12:26:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '16ceee1d-b3d1-4ee3-88a5-c10a0e029e3a' User entered '06 Sep 2020 12:26'	System	06 Sep 2020 16:26:53
	System	06 Sep 2020 16:26:53

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 14:45:21

US3402204

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:28:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 14:45:21

US3402204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	14 Sep 2020 13:56:12
	(b) (4)	

US3402204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '7 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 13:56:12

US3402204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	14 Sep 2020 13:56:12

US3402204

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Traci Hull (b) (4)	14 Sep 2020 13:56:12

US3402204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 13:56:16

US3402204

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	14 Sep 2020 13:56:16

US3402204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	14 Sep 2020 16:11:25

US3402204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '14 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	14 Sep 2020 16:11:25
	(b) (4)	

US3402204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	14 Sep 2020 16:11:25

US3402204

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	(b) (4)	
	Tammy Kohn (b) (4)	14 Sep 2020 16:11:25
	(b) (4)	

US3402204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	14 Sep 2020 16:11:42

US3402204

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	14 Sep 2020 16:11:42

US3402204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	21 Sep 2020 17:16:31
	(b) (4)	

US3402204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered '21 Sep 2020'	Traci Hull (b) (4)	21 Sep 2020 17:16:31

US3402204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	21 Sep 2020 17:16:31

US3402204

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered empty.	Traci Hull (b) (4)	21 Sep 2020 17:16:31

US3402204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:29
User entered 'Yes (Y)'	Traci Hull (b) (4)	21 Sep 2020 17:16:35

US3402204

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	21 Sep 2020 17:16:35

US3402204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:04:54

US3402204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '28 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:04:54
	(b) (4)	

US3402204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Clinic (Clinic)'	Tammy Kohn (b) (4)	28 Sep 2020 13:04:54

US3402204

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'VISIT3'	System	28 Sep 2020 13:04:54

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '28 Sep 2020'	Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '08:34'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '28 Sep 2020 08:34'	System	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '36.6' C reason for change: New Information	Traci Hull (b) (4)	30 Sep 2020 18:19:23
User entered '97.9' F	Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Oral (Oral)'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered empty.	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29
	(b) (4)	

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '58'	Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'bpm'	System	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '14'	Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'breaths/min'	System	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '128'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '81'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'mmHg'	System	28 Sep 2020 13:05:29

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35

US3402204

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35

US3402204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'No (N)'	(b) (4)	
	Tammy Kohn (b) (4)	28 Sep 2020 13:05:35
	(b) (4)	

US3402204

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered empty.	(b) (4)	28 Sep 2020 13:05:35
	Tammy Kohn (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:48

US3402204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '28 Sep 2020'	Tammy Kohn (b) (4)	28 Sep 2020 13:05:48

US3402204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered '08:49'	Tammy Kohn (b) (4)	28 Sep 2020 13:05:48

US3402204

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered '28 Sep 2020 08:49'	System	28 Sep 2020 13:05:48

US3402204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 16:59:49
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Sep 2020 13:05:59

US3402204

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	28 Sep 2020 13:05:59

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 64'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-03T12:36:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3d356e37-d68e-4687-b1ab-d105e9dd1a54'	System	03 Oct 2020 16:36:29
User entered 'No (N)'	System	03 Oct 2020 16:36:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-03T12:36:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3d356e37-d68e-4687-b1ab-d105e9dd1a54'	System	03 Oct 2020 16:36:29
User entered 'No (N)'	System	03 Oct 2020 16:36:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-03T12:36:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3d356e37-d68e-4687-b1ab-d105e9dd1a54' User entered '03 Oct 2020 12:36:26'	System	03 Oct 2020 16:36:29
	System	03 Oct 2020 16:36:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '03 Oct 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '07 Oct 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 71'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-10T09:01:14', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0279a246-2cd7-40f9-8351-dad5ce919c6c'	System	10 Oct 2020 13:01:26
User entered 'No (N)'	System	10 Oct 2020 13:01:26

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-10T09:01:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0279a246-2cd7-40f9-8351-dad5ce919c6c'	System	10 Oct 2020 13:01:26
User entered 'No (N)'	System	10 Oct 2020 13:01:26

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-10T09:01:23', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0279a246-2cd7-40f9-8351-dad5ce919c6c' User entered '10 Oct 2020 09:01:23'	System	10 Oct 2020 13:01:26
	System	10 Oct 2020 13:01:26

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '10 Oct 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '14 Oct 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 78'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-17T10:57:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0fc7ef58-0fe5-472a-8753-b10435c98659'	System	17 Oct 2020 14:57:23
User entered 'No (N)'	System	17 Oct 2020 14:57:23

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-17T10:57:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0fc7ef58-0fe5-472a-8753-b10435c98659'	System	17 Oct 2020 14:57:23
User entered 'No (N)'	System	17 Oct 2020 14:57:23

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-17T10:57:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0fc7ef58-0fe5-472a-8753-b10435c98659' User entered '17 Oct 2020 10:57:21'	System	17 Oct 2020 14:57:23
	System	17 Oct 2020 14:57:23

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '17 Oct 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '21 Oct 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 92'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-31T10:25:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '80be140c-880c-426f-ba90-f34b11f27c26'	System	31 Oct 2020 14:25:42
User entered 'No (N)'	System	31 Oct 2020 14:25:42

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-31T10:25:34', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '80be140c-880c-426f-ba90-f34b11f27c26'	System	31 Oct 2020 14:25:42
User entered 'No (N)'	System	31 Oct 2020 14:25:42

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-10-31T10:25:39', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '80be140c-880c-426f-ba90-f34b11f27c26' User entered '31 Oct 2020 10:25:39'	System	31 Oct 2020 14:25:42
	System	31 Oct 2020 14:25:42

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '31 Oct 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '04 Nov 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 99'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-07T07:11:08', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e62d781-fcdf-4f15-8bda-929765e57338'	System	07 Nov 2020 12:11:24
User entered 'No (N)'	System	07 Nov 2020 12:11:24

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-07T07:11:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e62d781-fcdf-4f15-8bda-929765e57338'	System	07 Nov 2020 12:11:24
User entered 'No (N)'	System	07 Nov 2020 12:11:24

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-07T07:11:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '3e62d781-fcdf-4f15-8bda-929765e57338' User entered '07 Nov 2020 07:11:20'	System	07 Nov 2020 12:11:24
	System	07 Nov 2020 12:11:24

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '07 Nov 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '11 Nov 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered 'Day 106'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-14T08:58:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '584579ee-1814-4875-929e-ccf8fc42ad09' User entered 'No (N)'	System	14 Nov 2020 13:58:29
	System	14 Nov 2020 13:58:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-14T08:58:24', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '584579ee-1814-4875-929e-ccf8fc42ad09'	System	14 Nov 2020 13:58:29
User entered 'No (N)'	System	14 Nov 2020 13:58:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-14T08:58:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '584579ee-1814-4875-929e-ccf8fc42ad09' User entered '14 Nov 2020 08:58:27'	System	14 Nov 2020 13:58:29
	System	14 Nov 2020 13:58:29

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '14 Nov 2020 00:01'	System	03 Aug 2020 15:35:49

US3402204

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:13
Data entry locked.	System	03 Aug 2020 15:35:49
User entered '18 Nov 2020 23:59'	System	03 Aug 2020 15:35:49

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-20T19:34:49', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7ccb22d5-1f3b-42f7-8ca4-9d47d0ba9eee' User entered 'No (N)'	System	21 Nov 2020 00:38:40
	System	21 Nov 2020 00:38:40

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-20T19:34:54', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7ccb22d5-1f3b-42f7-8ca4-9d47d0ba9eee'	System	21 Nov 2020 00:38:40
User entered 'No (N)'	System	21 Nov 2020 00:38:40

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-20T19:34:57', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '7ccb22d5-1f3b-42f7-8ca4-9d47d0ba9eee' User entered '20 Nov 2020 19:34:57'	System	21 Nov 2020 00:38:40
	System	21 Nov 2020 00:38:40

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-25T06:15:18', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '239b5515-b66a-4144-8450-c03067f69e7f' User entered 'No (N)'	System	25 Nov 2020 11:15:34
	System	25 Nov 2020 11:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-25T06:15:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '239b5515-b66a-4144-8450-c03067f69e7f' User entered 'No (N)'	System	25 Nov 2020 11:15:34
	System	25 Nov 2020 11:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-11-25T06:15:30', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '239b5515-b66a-4144-8450-c03067f69e7f' User entered '25 Nov 2020 06:15:30'	System	25 Nov 2020 11:15:34
	System	25 Nov 2020 11:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-04T12:00:26', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5cc0b4f8-5e70-4dbf-a6c0-5926cd5ce858'	System	04 Dec 2020 17:00:41
User entered 'No (N)'	System	04 Dec 2020 17:00:41

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-04T12:00:32', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5cc0b4f8-5e70-4dbf-a6c0-5926cd5ce858'	System	04 Dec 2020 17:00:41
User entered 'No (N)'	System	04 Dec 2020 17:00:41

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-04T12:00:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5cc0b4f8-5e70-4dbf-a6c0-5926cd5ce858' User entered '04 Dec 2020 12:00:36'	System	04 Dec 2020 17:00:41
	System	04 Dec 2020 17:00:41

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-09T06:23:09', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6f349ffb-f53d-4453-91af-d907ec94fece'	System	09 Dec 2020 11:23:23
User entered 'No (N)'	System	09 Dec 2020 11:23:23

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-09T06:23:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6f349ffb-f53d-4453-91af-d907ec94fece'	System	09 Dec 2020 11:23:23
User entered 'No (N)'	System	09 Dec 2020 11:23:23

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-09T06:23:20', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '6f349ffb-f53d-4453-91af-d907ec94fece' User entered '09 Dec 2020 06:23:20'	System	09 Dec 2020 11:23:23
	System	09 Dec 2020 11:23:23

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-16T06:28:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '00469553-f216-45ed-877b-0dbf47ed80cb' User entered 'No (N)'	System	16 Dec 2020 11:28:48
	System	16 Dec 2020 11:28:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-16T06:28:42', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '00469553-f216-45ed-877b-0dbf47ed80cb' User entered 'No (N)'	System	16 Dec 2020 11:28:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-16T06:28:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '00469553-f216-45ed-877b-0dbf47ed80cb' User entered '16 Dec 2020 06:28:46'	System	16 Dec 2020 11:28:48
	System	16 Dec 2020 11:28:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-23T06:33:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '30863872-631a-4331-a581-14d67b5228c0'	System	23 Dec 2020 11:33:43
User entered 'No (N)'	System	23 Dec 2020 11:33:43

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-23T06:33:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '30863872-631a-4331-a581-14d67b5228c0'	System	23 Dec 2020 11:33:43
User entered 'No (N)'	System	23 Dec 2020 11:33:43

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-23T06:33:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '30863872-631a-4331-a581-14d67b5228c0' User entered '23 Dec 2020 06:33:37'	System	23 Dec 2020 11:33:43
	System	23 Dec 2020 11:33:43

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-30T12:48:17', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'c69b300e-fee4dbc-b994-236e3fbef372' User entered 'No (N)'	System	30 Dec 2020 17:48:25

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-30T12:48:19', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'c69b300e-fee4dbc-b994-236e3fbef372' User entered 'No (N)'	System	30 Dec 2020 17:48:25

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2020-12-30T12:48:22', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'c69b300e-fee4-4dbc-b994-236e3fbef372' User entered '30 Dec 2020 12:48:22'	System	30 Dec 2020 17:48:25
	System	30 Dec 2020 17:48:25

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-06T06:30:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'a7f4f9eb-e15c-4342-9dc9-87600d6722c2'	System	07 Jan 2021 11:52:21
User entered 'No (N)'	System	07 Jan 2021 11:52:21

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-06T06:30:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'a7f4f9eb-e15c-4342-9dc9-87600d6722c2'	System	07 Jan 2021 11:52:21
User entered 'No (N)'	System	07 Jan 2021 11:52:21

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-06T06:30:42', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'a7f4f9eb-e15c-4342-9dc9-87600d6722c2' User entered '06 Jan 2021 06:30:42'	System	07 Jan 2021 11:52:21
	System	07 Jan 2021 11:52:21

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:19', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'Yes (Y)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'Yes (Y)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Please 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:31', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:41', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'Yes (Y)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '0'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '0'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '0'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '1'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '0'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:30:59', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered '0'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Please 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:31:04', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:31:13', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'Yes (Y)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Please 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:31:16', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95'	System	14 Jan 2021 21:31:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-14T16:31:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ba4fd59d-85d5-4bcb-b6d3-8c8ac8b62b95' User entered '14 Jan 2021 16:31:21'	System	14 Jan 2021 21:31:30

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:03:12', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'Yes (Y)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:03:58', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'No (N)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:06', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'Yes (Y)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '1'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '1'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered '1'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55
	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55
	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:21', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered '0'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Please 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:28', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:36', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'Yes (Y)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Please 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72'	System	20 Jan 2021 21:04:55
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-20T16:04:45', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'aa4aa611-80cd-40d9-820e-03cb027fdc72' User entered '20 Jan 2021 16:04:45'	System	20 Jan 2021 21:04:55
	System	20 Jan 2021 21:04:55

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-27T18:50:38', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b1c4446-d3e1-4e39-a231-930109dc949a' User entered 'No (N)'	System	27 Jan 2021 23:50:48
	System	27 Jan 2021 23:50:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-27T18:50:42', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b1c4446-d3e1-4e39-a231-930109dc949a'	System	27 Jan 2021 23:50:48
User entered 'No (N)'	System	27 Jan 2021 23:50:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-01-27T18:50:46', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '8b1c4446-d3e1-4e39-a231-930109dc949a' User entered '27 Jan 2021 18:50:46'	System	27 Jan 2021 23:50:48
	System	27 Jan 2021 23:50:48

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-06T17:57:25', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0856cb80-414a-4cf9-9dc2-cf4e7fe13e39'	System	07 Feb 2021 22:13:49
User entered 'No (N)'	System	07 Feb 2021 22:13:49

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-06T17:57:27', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0856cb80-414a-4cf9-9dc2-cf4e7fe13e39'	System	07 Feb 2021 22:13:49
User entered 'No (N)'	System	07 Feb 2021 22:13:49

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-06T17:57:29', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '0856cb80-414a-4cf9-9dc2-cf4e7fe13e39'	System	07 Feb 2021 22:13:49
User entered '06 Feb 2021 17:57:29'	System	07 Feb 2021 22:13:49

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-11T09:51:35', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '845c1f27-e606-4ae1-9ece-a2cd86e6646e' User entered 'No (N)'	System	13 Feb 2021 03:37:11
	System	13 Feb 2021 03:37:11

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-11T09:51:37', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '845c1f27-e606-4ae1-9ece-a2cd86e6646e' User entered 'No (N)'	System	13 Feb 2021 03:37:11

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-11T09:51:40', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '845c1f27-e606-4ae1-9ece-a2cd86e6646e' User entered '11 Feb 2021 09:51:40'	System	13 Feb 2021 03:37:11

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-17T06:29:50', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'bccd9518-4300-4124-9122-0c3ec148f144'	System	17 Feb 2021 11:29:58
User entered 'No (N)'	System	17 Feb 2021 11:29:58

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-17T06:29:52', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'bccd9518-4300-4124-9122-0c3ec148f144'	System	17 Feb 2021 11:29:58
User entered 'No (N)'	System	17 Feb 2021 11:29:58

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-17T06:29:55', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'bccd9518-4300-4124-9122-0c3ec148f144' User entered '17 Feb 2021 06:29:55'	System	17 Feb 2021 11:29:58
	System	17 Feb 2021 11:29:58

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-24T06:14:26-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '89cd0849-0da4-43bb-aa60-7baaa3f75de4' User entered 'No (N)'	System	27 Feb 2021 12:37:08
	System	27 Feb 2021 12:37:08

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-24T06:14:32-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '89cd0849-0da4-43bb-aa60-7baaa3f75de4' User entered 'No (N)'	System	27 Feb 2021 12:37:08
	System	27 Feb 2021 12:37:08

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-24T06:14:36-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '89cd0849-0da4-43bb-aa60-7baaa3f75de4' User entered '24 Feb 2021 11:14:36'	System	27 Feb 2021 12:37:08
	System	27 Feb 2021 12:37:08

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-05T12:03:25-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd60bc487-ae61-45dc-94cc-ea61afecf562'	System	05 Mar 2021 17:13:17
User entered 'No (N)'	System	05 Mar 2021 17:13:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-05T12:03:27-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd60bc487-ae61-45dc-94cc-ea61afecf562'	System	05 Mar 2021 17:13:17
User entered 'No (N)'	System	05 Mar 2021 17:13:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-05T12:03:29-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd60bc487-ae61-45dc-94cc-ea61afecf562'	System	05 Mar 2021 17:13:17
User entered '05 Mar 2021 12:03:29'	System	05 Mar 2021 17:13:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-12T20:28:01-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fe99f6dd-eb6c-4e2a-a793-5d572695f051'	System	13 Mar 2021 01:28:15
User entered 'No (N)'	System	13 Mar 2021 01:28:15

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-12T20:28:03-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fe99f6dd-eb6c-4e2a-a793-5d572695f051'	System	13 Mar 2021 01:28:15
User entered 'No (N)'	System	13 Mar 2021 01:28:15

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-12T20:28:07-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'fe99f6dd-eb6c-4e2a-a793-5d572695f051' User entered '12 Mar 2021 20:28:07'	System	13 Mar 2021 01:28:15
	System	13 Mar 2021 01:28:15

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-17T06:06:02-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ce462bc0-17ed-484d-af0b-3fa50bcd30b8'	System	17 Mar 2021 10:06:10
User entered 'No (N)'	System	17 Mar 2021 10:06:10

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-17T06:06:04-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ce462bc0-17ed-484d-af0b-3fa50bcd30b8'	System	17 Mar 2021 10:06:10
User entered 'No (N)'	System	17 Mar 2021 10:06:10

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-17T06:06:07-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'ce462bc0-17ed-484d-af0b-3fa50bcd30b8' User entered '17 Mar 2021 06:06:07'	System	17 Mar 2021 10:06:10
	System	17 Mar 2021 10:06:10

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-25T06:39:05-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5b4cc1a2-0760-48e4-964f-648c24de3eff' User entered 'No (N)'	System	25 Mar 2021 10:39:17
	System	25 Mar 2021 10:39:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-25T06:39:10-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5b4cc1a2-0760-48e4-964f-648c24de3eff' User entered 'No (N)'	System	25 Mar 2021 10:39:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-03-25T06:39:14-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '5b4cc1a2-0760-48e4-964f-648c24de3eff' User entered '25 Mar 2021 06:39:14'	System	25 Mar 2021 10:39:17
	System	25 Mar 2021 10:39:17

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-01T06:52:16-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51b6a70c-a1c3-4e83-9b5e-a2835c9dce2d' User entered 'No (N)'	System	01 Apr 2021 10:52:26
	System	01 Apr 2021 10:52:26

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-01T06:52:19-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51b6a70c-a1c3-4e83-9b5e-a2835c9dce2d' User entered 'No (N)'	System	01 Apr 2021 10:52:26

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-01T06:52:21-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '51b6a70c-a1c3-4e83-9b5e-a2835c9dce2d' User entered '01 Apr 2021 06:52:21'	System	01 Apr 2021 10:52:26
	System	01 Apr 2021 10:52:26

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-07T06:15:24-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15a48783-3b7d-48da-9268-72d3293cb8cc'	System	07 Apr 2021 10:15:34
User entered 'No (N)'	System	07 Apr 2021 10:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-07T06:15:26-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15a48783-3b7d-48da-9268-72d3293cb8cc'	System	07 Apr 2021 10:15:34
User entered 'No (N)'	System	07 Apr 2021 10:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-07T06:15:30-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '15a48783-3b7d-48da-9268-72d3293cb8cc'	System	07 Apr 2021 10:15:34
User entered '07 Apr 2021 06:15:30'	System	07 Apr 2021 10:15:34

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-15T06:49:22-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9ef91c17-762c-437d-8fa5-41d06162c8ca' User entered 'No (N)'	System	15 Apr 2021 10:49:29
	System	15 Apr 2021 10:49:29

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-15T06:49:24-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9ef91c17-762c-437d-8fa5-41d06162c8ca'	System	15 Apr 2021 10:49:29
User entered 'No (N)'	System	15 Apr 2021 10:49:29

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-15T06:49:26-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '9ef91c17-762c-437d-8fa5-41d06162c8ca' User entered '15 Apr 2021 06:49:26'	System	15 Apr 2021 10:49:29
	System	15 Apr 2021 10:49:29

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-22T06:30:15-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd294ad39-2fd2-4fd8-9c06-2fe59c1cbd05'	System	22 Apr 2021 10:30:24
User entered 'No (N)'	System	22 Apr 2021 10:30:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

Have you been exposed to someone with 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 (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-22T06:30:17-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd294ad39-2fd2-4fd8-9c06-2fe59c1cbd05'	System	22 Apr 2021 10:30:24
User entered 'No (N)'	System	22 Apr 2021 10:30:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-04-22T06:30:20-04:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: 'd294ad39-2fd2-4fd8-9c06-2fe59c1cbd05'	System	22 Apr 2021 10:30:24
User entered '22 Apr 2021 06:30:20'	System	22 Apr 2021 10:30:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 11:43:24

US3402204

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:28:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:43:24
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 11:43:24

US3402204

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:54

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 21:23:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-27T07:37:14-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '29e8afc5-c0a1-4625-ab69-f82377e4b94c'	System	27 Feb 2021 12:37:27
User entered 'No (N)'	System	27 Feb 2021 12:37:27

US3402204

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:28:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 21:23:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B472FE36-D1EE-4A8E-A86A-4E3ABE7471C7)', Time: '2021-02-27T07:37:24-05:00', User OID: 'PatientReportedOutcome (US3402204)', ODM File OID: '29e8afc5-c0a1-4625-ab69-f82377e4b94c' User entered '27 Feb 2021 12:37:24'	System	27 Feb 2021 12:37:27
	System	27 Feb 2021 12:37:27

US3402204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:08
User entered 'Yes (Y)'	(b) (4)	26 Oct 2020 17:47:11
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:08
User entered '26 Oct 2020'	Traci Hull (b) (4)	26 Oct 2020 17:47:11

US3402204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:08
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	26 Oct 2020 17:47:11

US3402204

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:08
User entered empty.	Traci Hull (b) (4)	26 Oct 2020 17:47:11

US3402204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:08
User entered 'Yes (Y)'	Traci Hull (b) (4)	26 Oct 2020 17:47:00

US3402204

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:46:35
User entered 'I'	System	26 Oct 2020 17:47:00

US3402204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	30 Nov 2020 19:43:27
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '30 Nov 2020'	Traci Hull (b) (4)	30 Nov 2020 19:43:27

US3402204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	30 Nov 2020 19:43:27

US3402204

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	30 Nov 2020 19:43:27
	(b) (4)	

US3402204

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	30 Nov 2020 19:43:31
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User entered 'I'	System	30 Nov 2020 19:43:31

US3402204

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Dec 2020 15:47:57

US3402204

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '28 Dec 2020'	(b) (4) Tammy Kohn (b) (4)	28 Dec 2020 15:47:57

US3402204

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	28 Dec 2020 15:47:57

US3402204

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	28 Dec 2020 15:47:57
	(b) (4)	

US3402204

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	28 Dec 2020 15:48:08

US3402204

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User entered 'I'	System	28 Dec 2020 15:48:08

US3402204

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	02 Feb 2021 17:50:56
	(b) (4)	

US3402204

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '29 Jan 2021'	Traci Hull (b) (4)	02 Feb 2021 17:50:56

US3402204

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	02 Feb 2021 17:50:56

US3402204

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:28:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	02 Feb 2021 17:50:56
	(b) (4)	

US3402204

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	02 Feb 2021 17:50:43
	(b) (4)	

US3402204

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:27
User entered 'I'	System	02 Feb 2021 17:50:43

US3402204

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Query 'Per CDM: Please complete the Vital Signs form. Thank you! ' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 19:19:29
User opened query 'Per CDM: Please complete the Vital Signs form. Thank you! ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:15:07
Query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 2 Mar 2021, however, 'Were vital signs assessed?' is not completed at this visit but at Participant Decision Visit / OL-D1 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the assessment data should be entered at both visits per sponsor. Please review and update as appropriate. Thank You!' canceled (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:14:37
User opened query 'Per CDM: Visit 4 Day 209 and Participant Decision Visit / OL-D1 are both dated 2 Mar 2021, however, 'Were vital signs assessed?' is not completed at this visit but at Participant Decision Visit / OL-D1 'Were vital signs assessed?' is YES and data is present. If the visits occurred on the same day, then the assessment data should be entered at both visits per sponsor. Please review and update as appropriate. Thank You!' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 19:13:39
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:29:48

US3402204

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:29:48
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:29:48

US3402204

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered 'VISIT4'	System	02 Mar 2021 16:29:48

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered empty.	System	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered empty.	System	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered empty.	System	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered empty.	System	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4) Tammy Kohn (b) (4)	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered empty.	System	30 Mar 2021 19:16:33

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31

US3402204

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31

US3402204

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'No (N)'	(b) (4)	02 Mar 2021 16:29:54
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered empty.	(b) (4)	02 Mar 2021 16:29:54
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 16:30:07
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:30:07
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '10:31'	(b) (4)	02 Mar 2021 16:30:07
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered '2 Mar 2021 10:31'	System	02 Mar 2021 16:30:07

US3402204

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 16:30:12
	Traci Hull (b) (4)	
	(b) (4)	

US3402204

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:28:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:31
User entered 'I'	System	02 Mar 2021 16:30:12

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:54

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:22:05
User entered '11 Dec 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Feb 2021 14:25:10
User entered '11 Jan 2021'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:10:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:54

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:22:10
User entered '14:00'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:10:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:54

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:32
User entered '11 Dec 2020 14:00'	System	26 Feb 2021 14:25:10
User entered '11 Jan 2021 14:00'	System	11 Jan 2021 21:10:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:54

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:22:20
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:22:14
Query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' answered with 'DATA UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:58:06
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	15 Feb 2021 19:57:59
User opened query 'Per ETRTR: Please consider updating answer to "Clinic Visit - Unscheduled" because Illness Visit did not occur during a Protocol Scheduled Visit, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 22:11:18
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	-Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:10:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:28:54

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:32
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:22:24
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:10:54

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 1 (Day 1)'	(b) (4) Traci Hull (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:14

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 2 (Day 2)'	(b) (4) Traci Hull (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '07 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:12:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 3 (Day 3)'	(b) (4) Traci Hull (b) (4)	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '08 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:13:44

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 4 (Day 4)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '09 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:18

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 5 (Day 5)'	(b) (4) Traci Hull (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '10 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:14:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 6 (Day 6)'	(b) (4) Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '99'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '37.3' C	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:15:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 7 (Day 7)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '12 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User closed query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 15:31:55
Query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' answered with 'TEMPERATURE UPDATED' (Site from DM).	Tammy Kohn (b) (4)	24 Feb 2021 18:57:16
User entered '98.4' F reason for change: Data Entry Error	(b) (4)	24 Feb 2021 18:57:04
User opened query 'Per CDM: Per sponsor review, please confirm unit for temperature. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 00:19:17
User entered '98.4' C	Traci Hull (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 8 (Day 8)'	(b) (4) Traci Hull (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '13 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '99.7' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:05:57

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 9 (Day 9)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '14 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '98'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:06:47

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 10 (Day 10)'	(b) (4) Traci Hull (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '15 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 11 (Day 11)'	(b) (4) Traci Hull (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '16 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '95'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '98.7' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:07:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 12 (Day 12)'	(b) (4) Traci Hull (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '17 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)' reason for change: Data Entry Error	Traci Hull (b) (4)	21 Jan 2021 16:08:56
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:08:31

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 13 (Day 13)'	(b) (4) Traci Hull (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '18 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '90'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:09:37

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.1' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:09:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 14 (Day 14)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '91'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.6' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (14)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:33

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 15 (Day 15)'	(b) (4) Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '20 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '94'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	21 Jan 2021 16:10:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.7' F	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (15)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:10:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 16 (Day 16)'	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '21 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '88'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.7' F	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (16)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 17 (Day 17)'	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '22 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '91'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.7' F	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Moderate (Moderate)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (17)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:36

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 18 (Day 18)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '23 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '92' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Jan 2021 12:58:29
User entered '97'	(b) (4) Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.2' F reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Jan 2021 12:58:29
User entered '97.4' F	(b) (4) Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (18)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:51:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 19 (Day 19)'	(b) (4) Tammy Kohn (b) (4)	26 Jan 2021 12:53:20
	(b) (4)	

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '24 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.6' F	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (19)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:53:20

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 20 (Day 20)'	(b) (4) Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	(b) (4) Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:54:59

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 12:41:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Jan 2021 12:41:49
User entered '25 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:49
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Jan 2021 12:39:59
User entered empty.	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 12:54:59

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Form: Symptom Log (20)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	(b) (4)	26 Jan 2021 12:54:59
	Tammy Kohn (b) (4)	
	(b) (4)	

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Form: Symptom Log (20)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.6' F	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

Difficulty Breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (20)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4)	27 Jan 2021 12:39:59
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	27 Jan 2021 12:33:32
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	26 Jan 2021 12:54:59

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Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 21 (Day 21)'	(b) (4) Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '95'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.9' F	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (21)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	27 Jan 2021 12:41:13

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 22 (Day 22)'	(b) (4) Tammy Kohn (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '27 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '95'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	28 Jan 2021 14:33:29

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.8' F	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (22)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	28 Jan 2021 14:33:29

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 23 (Day 23)'	(b) (4) Tammy Kohn (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '28 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '95'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.1' F	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (23)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	29 Jan 2021 13:52:58

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 24 (Day 24)'	(b) (4) Tammy Kohn (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '29 Jan 2021'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.2' F	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per source this is marked as Mild. Please verify and update accordingly. Thank you!' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:38:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:38:48
Query 'Per source this is marked as Mild. Please verify and update accordingly. Thank you!' answered with 'updated' (Site from CRA).	Tammy Kohn (b) (4)	14 Apr 2021 18:13:32
DataPoint Un-verified.	Tammy Kohn (b) (4)	14 Apr 2021 18:13:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	14 Apr 2021 18:13:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:02:42
User opened query 'Per source this is marked as Mild. Please verify and update accordingly. Thank you!' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:59:11
User entered 'None (None)'	Tammy Kohn (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

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[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (24)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	30 Jan 2021 15:15:52

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 25 (Day 25)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 14:18:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '30 Jan 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.3' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (25)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 26 (Day 26)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '31 Jan 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.4' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (26)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:18:54

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 27 (Day 27)'	(b) (4) Traci Hull (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '1 Feb 2021'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '99'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

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Folder: Covid-19 Assessment 11 Dec 2020

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[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.7' F	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (27)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:19:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 28 (Day 28)'	(b) (4) Traci Hull (b) (4)	03 Feb 2021 13:35:50

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '2 Feb 2021'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '98'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	03 Feb 2021 13:35:50

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.8' F	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (28)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	03 Feb 2021 13:35:50

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 29 (Day 29)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '3 Feb 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '95'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	04 Feb 2021 14:57:04

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (29)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:57:04

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 30 (Day 30)'	(b) (4) Traci Hull (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '4 Feb 2021'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '98'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97.6' F	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (30)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Traci Hull (b) (4) (b) (4)	05 Feb 2021 13:35:56

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 31 (Day 31)'	(b) (4) Tammy Kohn (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '5 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered missing code ND - Not Done.	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'Mild (Mild)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (32)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:21:34

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 32 (Day 32)'	(b) (4) Tammy Kohn (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '6 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '96.5' F	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (33)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:23:37

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Day 33 (Day 33)'	(b) (4) Tammy Kohn (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '7 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '0'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '97'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User entered '%'	System	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered '962' F	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Symptom Log (34)

Generated On: 09 Jun 2021 17:28:54

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:26:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 17:02:42
User entered 'None (None)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:24:46

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:43
DataPoint Un-verified.	Jennifer Molstead (b) (4)	08 Mar 2021 22:41:32
User entered '11 Jan 2021' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Mar 2021 22:41:32
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:25:33
User entered '11 Dec 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Feb 2021 14:29:11
User entered '11 Jan 2021'	Traci Hull (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:25:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:25:38
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 Jan 2021 14:50:47
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 'AE ALREADY IN SYSTEM FOR COVID 19 DIAGNOSIS' (Site from System).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 16:23:54
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	18 Jan 2021 21:37:16
User entered 'Yes (Y)' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:16
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

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Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:34:44
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-DEC-2020" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "11-JAN-2021" for illness visit. Kindly review & confirm the correct collection date & update data as appropriate in EDC or Preclarus portal, else clarify.' (Site from DM). Query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-DEC-2020" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "11-JAN-2021" for illness visit. Kindly review & confirm the correct collection date & update data as appropriate in EDC or Preclarus portal, else clarify.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 08:35:34
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	08 Mar 2021 22:41:43
User entered '11 Jan 2021' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	08 Mar 2021 22:41:32
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated "11-DEC-2020" is recorded under Covid-19 Assessment in EDC; however, in PPD portal, it is recorded as "11-JAN-2021" for illness visit. Kindly review & confirm the correct collection date & update data as appropriate in EDC or Preclarus portal, else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 06:50:36
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:25:40
User entered '11 Dec 2020' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Feb 2021 14:29:11
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

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Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:25:42
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:25:44
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:25:46
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

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Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:27
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:30
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:28:54

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:01
User entered '1'	System	18 Jan 2021 21:37:16
User entered '0'	System	11 Jan 2021 21:11:11

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

Did the subject have Respiratory Rates \geq 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:41
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:44
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:47
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:50
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:26:52
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

US3402204

Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

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)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per CDM: Per sponsor review, Symptom Log reports several days with Low O2. However field response is No. Please review and reconcile.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:26:43
Query 'Per CDM: Per sponsor review, Symptom Log reports several days with Low O2. However field response is No. Please review and reconcile.' answered with 'INSPITE OF LOW O2 THE SUBJECT WAS NOT GIVEN O2. SUBJECT WAS PLACED ON PREDNISONE AND SCHEDULED WITH PULMONARY DR' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Apr 2021 15:18:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:38:53
User opened query 'Per CDM: Per sponsor review, Symptom Log reports several days with Low O2. However field response is No. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 17:49:00
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

Generated On: 09 Jun 2021 17:28:54

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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PaO2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
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User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Covid-19 Severity Assessment

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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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[ECMO?](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
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[Evidence of Shock Requires
Vasopressors](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
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User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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[Neurologic Dysfunction?](#)

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
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[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
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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)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:19
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:38:53
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	18 Jan 2021 21:37:59

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Folder: Covid-19 Assessment 11 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:28:54

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 23:27:30
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:29:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Traci Hull (b) (4)	08 Feb 2021 16:28:31
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 16:24:52

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	21 Jan 2021 16:13:02
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	11 Jan 2021 21:18:16
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:06:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:35:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 13JAN2021 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:09:38
User entered '13 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:13:02
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	21 Jan 2021 16:13:02
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	11 Jan 2021 21:18:16
	(b) (4)	

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:07:33
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:35:29
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 15JAN2021 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:09:47
User entered '15 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:13:02
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	21 Jan 2021 16:13:02
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	11 Jan 2021 21:18:16
	(b) (4)	

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:07:38
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:35:37
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17JAN2021 is recorded under Illness Visit Day 7 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:09:56
User entered '17 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:13:02
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4)	21 Jan 2021 16:13:02
	(b) (4)	
User entered 'No (N)'	Traci Hull (b) (4)	11 Jan 2021 21:18:16
	(b) (4)	

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:07:44
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:35:43
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19JAN2021 is recorded under Illness Visit Day 9 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 05:10:04
User entered '19 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:13:02
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	26 Jan 2021 13:01:28
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 25JAN2021. Hence please confirm the correct date for Day 14.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 07:39:11
Query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 25JAN2021. Hence please confirm the correct date for Day 14.' answered with 'PPD FORM HAS BEEN SENT TO CORRECT THE DATE TO THE 24JAN2021' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	21 Apr 2021 16:42:25
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 25JAN2021. Hence please confirm the correct date for Day 14.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:50:31
User closed query 'Per source this was collected on 24Jan2021. Please verify and update preclarus and EDC accordingly. Thank you. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:46:46 12 Apr 2021 19:46:44
Query 'Per source this was collected on 24Jan2021. Please verify and update preclarus and EDC accordingly. Thank you. ' answered with 'updated' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:21
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:16
User entered '24 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User opened query 'Per source this was collected on 24Jan2021. Please verify and update preclarus and EDC accordingly. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:42:18

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 14 Saliva Sample dated "24 JAN 2021", as it is reported as "25 JAN 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 17:20:54
Query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 14 Saliva Sample dated "24 JAN 2021", as it is reported as "25 JAN 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:15:05
User entered '25 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:14:57
User opened query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 14 Saliva Sample dated "24 JAN 2021", as it is reported as "25 JAN 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:10:51
User entered '24 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Jan 2021 13:01:28
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered 'Yes (Y)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:23:41
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 01FEB2021. Hence please confirm the correct date for Day 21 and amend EDC or PPD.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 07:39:15
Query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 01FEB2021. Hence please confirm the correct date for Day 21 and amend EDC or PPD.' answered with 'DCF FORM SENT TO CORRECT DATES' (Site from DM).	Traci Hull (b) (4) (b) (4)	21 Apr 2021 16:41:21
User opened query 'Per GCL LAB reconciliation: Saliva Re-query : PPD Central Lab sample is recorded with collection date 01FEB2021. Hence please confirm the correct date for Day 21 and amend EDC or PPD.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 07:51:53
User closed query 'Per source this was collected on 31Jan2021. Please verify and update preclarus and EDC accordingly. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:46:57 12 Apr 2021 19:46:54
Query 'Per source this was collected on 31Jan2021. Please verify and update preclarus and EDC accordingly. Thank you.' answered with 'UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:38
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:32
User entered '31 Jan 2021' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	12 Apr 2021 19:46:32
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:44:15
User opened query 'Per source this was collected on 31Jan2021. Please verify and update preclarus and EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:43:02

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 21 Saliva Sample dated "31 JAN 2021", as it is reported as "01 FEB 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 17:21:01
Query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 21 Saliva Sample dated "31 JAN 2021", as it is reported as "01 FEB 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:15:31
User entered '01 Feb 2021' reason for change: New Information	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:15:26
User opened query 'Per GCL Lab Recon: SALIVA: It appears there is Collection date mismatch for DAY 21 Saliva Sample dated "31 JAN 2021", as it is reported as "01 FEB 2021" in PPD GCL. Please confirm the Correct sample collection date in the response, and then please update correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 14:11:31
User entered '31 Jan 2021' reason for change: New Information	Traci Hull (b) (4) (b) (4)	02 Feb 2021 14:23:41
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:28:54

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:28:54

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User closed query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 08 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM). Query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 08 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' answered with 'DATA UPDATED' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 17:21:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:16:44
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:16:37
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:16:20
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 13:16:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 13:16:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:16:01
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 13:15:46
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:15:46
User opened query 'Per GCL Lab Recon: SALIVA: Per Preclarus report there is a record of COVID PCR Saliva Day 28 Sample with collection date of 08 FEB 2021 in PPD GCL, however the same is missing in EDC. Please update the missing sample details in this saliva log form in EDC. Thank you.' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6)	15 Feb 2021 13:17:10
	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:15
User entered '08 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	25 Feb 2021 13:16:01
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:18:16

US3402204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per ETRTR: COVID-19 Assessments Folder dated 08Feb20 seem related to Convalescent Day 28 for this period. Please consider removing data from COVID-19 Assessments folder dated 08Feb20 and complete "Convalescent Visit Day 28" instead as applicable, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:55:54
DataPoint Verified.	(b) (4), (b) (6)	26 Feb 2021 18:55:33
Query 'Per ETRTR: COVID-19 Assessments Folder dated 08Feb20 seem related to Convalescent Day 28 for this period. Please consider removing data from COVID-19 Assessments folder dated 08Feb20 and complete "Convalescent Visit Day 28" instead as applicable, thanks.' answered with 'THIS HAS BEEN UPDATED' (Site from CRA).	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:26:53
User opened query 'Per ETRTR: COVID-19 Assessments Folder dated 08Feb20 seem related to Convalescent Day 28 for this period. Please consider removing data from COVID-19 Assessments folder dated 08Feb20 and complete "Convalescent Visit Day 28" instead as applicable, thanks.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 22:15:48
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:09
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:13
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered 'SICKD1'	System	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '14:10'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered '11 Jan 2021 14:10'	System	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered missing code ND - Not Done.	Traci Hull (b) (4)	11 Jan 2021 21:17:25
DataPoint set to visible.	(b) (4) System	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered missing code ND - Not Done.	Traci Hull (b) (4)	11 Jan 2021 21:17:25
DataPoint set to visible.	(b) (4) System	11 Jan 2021 21:16:18

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '37.3' C	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered empty.	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '87'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered 'bpm'	System	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '16'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered 'breaths/min'	System	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '140'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered 'mmHg'	System	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:58:41
User entered '84'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User entered 'mmHg'	System	11 Jan 2021 21:17:25

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44

US3402204

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44

US3402204

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:59:40
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:36

US3402204

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:59:40
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:36

US3402204

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:28:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 18:59:46
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 08 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:40:48
Query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 08 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with '08 FEB 2021 IS RECORDED UNDER ILLNESS DAY 28 IN EDC ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	25 Feb 2021 13:14:20
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2: Sample dated 08 FEB 2021 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same SARS-CoV-2 serum is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 05:39:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:48

US3402204

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:33:44
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Feb 2021 19:00:08
User closed query 'Per Lab Recon: SARS-COV2: Sample dated 11 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:37:30
Query 'Per Lab Recon: SARS-COV2: Sample dated 11 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' answered with 'THE DATE IS CORRECT AS IS. THE LAB IS PRESENTLY INVESTIGATION THIS ISSUE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	04 Feb 2021 13:39:10
User opened query 'Per Lab Recon: SARS-COV2: Sample dated 11 JAN 2021 is missing in PPD GCL records, please kindly review the preclarus and update the PPD GCL with missing sample data. Please review if the sample has been shipped by providing in response the Accession number, Tracking number & shipping date, as this helps to track the sample with the details provided. Please kindly also review if site has to scan in barcodes through preclarus, so that the data reflects in PPD GCL records. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 03:40:18

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Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	11 Jan 2021 21:17:48

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	24 Feb 2021 16:09:19
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Feb 2021 15:52:48
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:26
User entered '8 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	24 Feb 2021 16:09:19
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	22 Feb 2021 15:52:48
User entered '7 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Feb 2021 15:44:14
User entered '7 Jan 2021'	Tammy Kohn (b) (4)	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:26
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 16:09:23
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:09:23
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 16:09:19
User closed query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	22 Feb 2021 15:52:53
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 15:52:53
User opened query 'Visit was not performed, however, Was visit performed at home or clinic is provided. Please review and reconcile.' (Site from System).	System	22 Feb 2021 15:52:48
User entered 'Home (Home)'	Tammy Kohn (b) (4) (b) (4)	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'SICKD28'	System	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '8 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '10:36'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered '8 Feb 2021 10:36'	System	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '181.5' cm	Tammy Kohn (b) (4)	24 Feb 2021 16:11:12
DataPoint set to visible.	(b) (4)	24 Feb 2021 16:09:19
DataPoint set to invisible.	System	22 Feb 2021 15:52:48
DataPoint set to visible.	System	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '30.8' kg	Tammy Kohn (b) (4)	24 Feb 2021 16:11:12
DataPoint set to visible.	(b) (4)	24 Feb 2021 16:09:19
DataPoint set to invisible.	System	22 Feb 2021 15:52:48
DataPoint set to visible.	System	22 Feb 2021 15:43:35

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Feb 2021 16:11:46
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	24 Feb 2021 16:11:46
User entered '36.2' C reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:46
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	24 Feb 2021 16:11:12
User entered '35.8' C	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered 'Oral (Oral)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered empty.	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '85'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'bpm'	System	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '16'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'breaths/min'	System	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '122'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:44
User entered '78'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User entered 'mmHg'	System	24 Feb 2021 16:11:12

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40

US3402204

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:28:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:55
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:13:06

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Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:28:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:44:55
User entered '8 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:13:06

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:28:54

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:46:04
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:13:17

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Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 17:28:54

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 23:52:40
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:46:04
User entered '8 Feb 2021'	Tammy Kohn (b) (4) (b) (4)	24 Feb 2021 16:13:17

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 16:30:24
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:30:24
	(b) (4)	

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:30:24

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

Form: Visit Date

Generated On: 09 Jun 2021 17:28:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User entered 'UNBLND_DECIDE'	System	02 Mar 2021 16:30:24

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:31:10
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '0'	(b) (4) Tammy Kohn (b) (4)	09 Apr 2021 13:15:36
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:13:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 16:31:10
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Apr 2021 05:57:31
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:15:39
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:15:36
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:40:15
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:13:07

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '02 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:31:10
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:31:10

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:31:10

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Placebo (Placebo)'	(b) (4) Traci Hull (b) (4) (b) (4)	02 Mar 2021 16:31:10

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'No (N)'	(b) (4)	02 Mar 2021 16:31:10
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User entered '1'	System	02 Mar 2021 16:31:10

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

Form: Unblinding

Generated On: 09 Jun 2021 17:28:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User entered empty.	System	02 Mar 2021 16:31:10

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	02 Mar 2021 16:31:26

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:31:26
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '10:31'	(b) (4)	02 Mar 2021 16:31:26
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:28:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User entered '2 Mar 2021 10:31'	System	02 Mar 2021 16:31:26

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 16:31:42
	Traci Hull (b) (4)	
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:31:42
	(b) (4)	

US3402204

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:54

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '10:19'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 16:31:42
	(b) (4)	

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:28:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:33
User entered '2 Mar 2021 10:19'	System	02 Mar 2021 16:31:42

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:28:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 02:50:19
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	18 Jan 2021 21:38:16
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 19:52:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:43:32
User entered	System	19 Jan 2021 20:43:28
'USA-US059-2021-mRNA-1273-P301000004'		
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 20:43:28

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 04:10:20
Query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4)	29 Jan 2021 21:21:32
	(b) (4)	
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)	29 Jan 2021 21:21:23
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 21:21:23
	(b) (4)	
Data point term sent to Coder	System	29 Jan 2021 21:21:09
Coding entries removed.	Tammy Kohn (b) (4)	29 Jan 2021 21:20:54
	(b) (4)	
User entered 'COVID-19' reason for change: Data Entry Error	Tammy Kohn (b) (4)	29 Jan 2021 21:20:54
	(b) (4)	
User opened query 'Per CDM: Per CCGs, positive Covid-19 AEs should be recorded as COVID-19 or SYMPTOMATIC COVID-19. Please review and update. ' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 20:27:35
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)	18 Jan 2021 21:41:13
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Jan 2021 21:41:13
	(b) (4)	
Data point term sent to Coder	System	18 Jan 2021 21:40:33
User entered 'Sars Covid-19'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:03:30
Query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	08 Mar 2021 22:35:35
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	08 Mar 2021 22:35:22
	(b) (4)	
User opened query 'Per DM CLR: Please review if this is a confirmed infection if so, per ECGs: Any confirmed SARS-Cov 2 infection/COVID-19 should be recorded as an MAAE. Review and update if applicable. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 15:23:13
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '06 Jan 2021'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:44:07
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 'END DATE OF 06 FEB 2021 WAS ADDED' (Site from Safety).	Tammy Kohn (b) (4)	16 Mar 2021 16:43:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Mar 2021 16:43:18
	(b) (4)	
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)	12 Mar 2021 21:42:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Jan 2021 16:23:25
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '06 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4)	16 Mar 2021 16:43:18
	(b) (4)	
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 22:05:26
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 'NOT RECOVERED AS OF YET ' (Site from Safety).	Tammy Kohn (b) (4)	29 Jan 2021 21:21:43
	(b) (4)	
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)	27 Jan 2021 17:28:36
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Jan 2021 16:23:25
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	18 Jan 2021 21:40:21
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:40:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 16:23:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 16:23:13
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	22 Jan 2021 16:23:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 21:40:21
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'I'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:44:11
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'SUBJECT HAS RECOVERED ' (Site from Safety).	Tammy Kohn (b) (4)	16 Mar 2021 16:43:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4)	
	(b) (4)	16 Mar 2021 16:43:18
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 21:42:29
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 22:05:34
	(b) (4), (b) (6)	
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'NOT RECOVERED YET STILL IN CONVALESCENCE STAGE' (Site from Safety).	Tammy Kohn (b) (4)	29 Jan 2021 21:22:35
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Jan 2021 17:28:52
	(b) (4), (b) (6)	
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
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).	(b) (4), (b) (6)	08 Feb 2021 22:05:47
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 'STILL IN CONVALESCENCE PHASE' (Site from Safety).	Tammy Kohn (b) (4)	29 Jan 2021 21:22:56
	(b) (4)	
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)	27 Jan 2021 17:29:09
User entered empty.	Jennifer Molstead (b) (4)	18 Jan 2021 21:40:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 16:23:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:28:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 22:35:22
User entered '0'	System	18 Jan 2021 21:40:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:07
User entered	System	02 Feb 2021 13:45:39
'USA-US059-2021-mRNA-1273-P301000007'		
User entered 'New'	(b) (4), (b) (6)	02 Feb 2021 13:45:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Cardiac infections, PT: Pericarditis infective, LLT: Acute infective pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 20:58:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 20:58:32
	(b) (4)	
Data point term sent to Coder	System	01 Feb 2021 20:43:06
User entered 'Acute Infective Pericarditis'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '30 Jan 2021'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Feb 2021 20:42:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:35:10
DataPoint Un-verified.	Jennifer Molstead (b) (4)	16 Apr 2021 15:58:57
	(b) (4)	
Signature has been broken.	Jennifer Molstead (b) (4)	16 Apr 2021 15:58:57
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	16 Apr 2021 15:58:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:42:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 20:42:38
User entered 'No (N)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 20:42:21
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

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. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 18:23:14
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available ? ' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 17:48:37
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 'Their will be no end date until the subject goes to get an ECG done.' (Site from Safety).	Tammy Kohn (b) (4) (b) (4)	28 Apr 2021 13:01:23
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)	27 Apr 2021 22:20:40
User signature succeeded.	Frank Eder (b) (4) (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:12
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 16:18:55
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Apr 2021 16:18:55
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Apr 2021 15:58:57
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	16 Apr 2021 15:58:57
Signature has been broken.	Jennifer Molstead (b) (4) (b) (4)	16 Apr 2021 15:58:57
User entered empty; reason for change Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	16 Apr 2021 15:58:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '31 Jan 2021'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 22:20:44
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)	26 Apr 2021 18:20:15
User entered empty.	System	01 Feb 2021 20:42:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

Severity

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'PV Query: Since the subject was hospitalized for the event of acute infective pericarditis, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:26:43
Query 'PV Query: Since the subject was hospitalized for the event of acute infective pericarditis, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	08 Feb 2021 19:02:21
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	08 Feb 2021 19:02:14
	(b) (4)	
User opened query 'PV Query: Since the subject was hospitalized for the event of acute infective pericarditis, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:27:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'I'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '30 Jan 2021'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:26:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	08 Feb 2021 20:56:42
	(b) (4)	
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:28:12
User entered '31 Jan 2021'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'No (N)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '0'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'I'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 10:37:30
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'line 2 and 3 are both during this time 30Jan2021' (Site from DM).	Tammy Kohn (b) (4)	25 Mar 2021 12:26:36
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:35:35
User entered 'I'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 15:48:06
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:16:01
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'THERE IS NO END DATE.' (Site from Safety).	Traci Hull (b) (4)	26 Apr 2021 18:51:19
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 18:21:02
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:35:22
DataPoint Un-verified.	Jennifer Molstead (b) (4)	16 Apr 2021 16:18:55
Signature has been broken.	Jennifer Molstead (b) (4)	16 Apr 2021 16:18:55
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	16 Apr 2021 16:18:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:42:21
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:51:54
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User closed query 'Per DM CLR: Per SAE Narrative "Fentanyl" was noted. However, this is not recorded in the CM eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM). Query 'Per DM CLR: Per SAE Narrative "Fentanyl" was noted. However, this is not recorded in the CM eCRF. Update as appropriate. Otherwise, provide clarification.' answered with 'Subject had stated he was given fentanyl. I have removed for now. Will relook at records' (Site from DM). User entered 'SUBJECT SUFFERED WHAT HE DEEMED SEVER CHEST PAIN WHILE DRIVING. SUBJECT WENT TO WALKING WHERE THEY DID AN ECG COMPLETED 30JAN2021 AND SENT THE SUBJECT TO THE EMERGENCY ROOM. SUBJECT WAS GIVEN NITRO, AND ASPIRIN. SUBJECT WAS EVALUATED BY CARDIOLOGY AND WAS SENT FOR A CARDIAC CATHETERIZATION COMPLETED 30JAN2021. THE CATH SHOWED NO HEART MUSCLE DAMAGE. HE WAS DIAGNOSED WITH ACUTE PERICARDITIS. SUBJECT WAS DISCHARGED HOME ON COLCHICINE 0.6MG PO DAILY, AND NAPROXEN 500MG PO BID. SUBJECT WAS ALREADY KNOWN TO BE COVID POSITIVE. NO COVID TESTING WAS PERFORMED.' reason for change: Per Query Resolution	(b) (4), (b) (6)	09 Mar 2021 06:04:20
User opened query 'Per DM CLR: Per SAE Narrative "Fentanyl" was noted. However, this is not recorded in the CM eCRF. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	Jennifer Molstead (b) (4)	08 Mar 2021 22:38:48
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	Jennifer Molstead (b) (4)	08 Mar 2021 22:38:43
	(b) (4), (b) (6)	17 Feb 2021 15:33:04
	(b) (4), (b) (6)	09 Feb 2021 16:26:31

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide date and results of ECG and cardiac catheterization.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 16:26:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	08 Feb 2021 19:02:40
Query 'PV Query: Please provide date and results of ECG and cardiac catheterization.' answered with 'Updated' (Site from Safety).	Jennifer Molstead (b) (4)	08 Feb 2021 19:02:35
User entered 'SUBJECT SUFFERED WHAT HE DEEMED SEVER CHEST PAIN WHILE DRIVING. SUBJECT WENT TO WALKING WHERE THEY DID AN ECG completed 30Jan2021 AND SENT THE SUBJECT TO THE EMERGENCY ROOM. SUBJECT WAS GIVEN NITRO, FENTANYL, AND ASPIRIN. SUBJECT WAS EVALUATED BY CARDIOLOGY AND WAS SENT FOR A CARDIAC CATHETERIZATION Completed 30Jan2021. THE CATH SHOWED NO HEART MUSCLE DAMAGE. HE WAS DIAGNOSED WITH ACUTE PERICARDITIS. SUBJECT WAS DISCHARGED HOME ON COLCHICINE 0.6MG PO DAILY, AND NAPROXEN 500MG PO BID. Subject was already known to be covid positive. No Covid testing was performed.' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	08 Feb 2021 19:02:14
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:26:43
User opened query 'PV Query: Please provide date and results of ECG and cardiac catheterization.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 18:26:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject suffered what he deemed sever chest pain while driving. Subject went to walking where they did an ECG and sent the subject to The emergency room. Subject was given Nitro, Fentanyl, and Aspirin. Subject was evaluated by cardiology and was sent for a cardiac catherization. The Cath showed no heart muscle damage. he was diagnosed with acute pericarditis. subject was discharged home on Colchicine 0.6mg po daily, and Naproxen 500mg po BID.'	Jennifer Molstead (b) (4)	(b) (4) 01 Feb 2021 20:42:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:42:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Feb 2021 20:42:21

US3402204

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:28:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	01 Feb 2021 20:42:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
User closed query 'Per source - please add:	(b) (4), (b) (6)	20 Apr 2021 15:14:59
Con Meds - Colchicine - 0.12mg, PO, Bid; Acute Pericarditis, 01Feb2021 - Ongoing. Not taken for solicited event.		
Thank you.' (Site from CRA).		
Query 'Per source - please add:	Tammy Kohn (b) (4)	17 Apr 2021 16:34:41
	(b) (4)	
Con Meds - Colchicine - 0.12mg, PO, Bid; Acute Pericarditis, 01Feb2021 - Ongoing. Not taken for solicited event.		
Thank you.' answered with 'ADDED Colchicine - 0.12mg, PO, Bid; Acute Pericarditis, 01Feb2021 - Ongoing. Not taken for solicited event. Thank you. ' (Site from CRA).		
User opened query 'Per source - please add:	(b) (4), (b) (6)	12 Apr 2021 20:06:40
Con Meds - Colchicine - 0.12mg, PO, Bid; Acute Pericarditis, 01Feb2021 - Ongoing. Not taken for solicited event.		
Thank you.' (Site from CRA).		
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:37
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Yes (Y)'	Traci Hull (b) (4)	03 Aug 2020 19:52:26
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	12 Apr 2021 20:02:08 12 Apr 2021 20:01:15
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6)	12 Apr 2021 20:00:50 12 Apr 2021 20:00:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:57:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:57:13
Data point term sent to Coder User entered 'allopurinol'	System Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:14 03 Aug 2020 19:56:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 19:03:53
Query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'left leg' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:07:31
User opened query 'Per DM CLR: Please update the indication to reflect the location of GOUT (e.g., Generalized, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:37:50
User entered 'gout'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '300'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:56:13
User entered 'un UNK 2017'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 19:56:13

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:30
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:52
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 20:40:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 20:40:12
Data point term sent to Coder	System	03 Aug 2020 19:57:15
User entered 'aspirin'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'cardiac prophylaxis'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '81'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:15
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:45
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:56:57
User entered 'un UNK 2000'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 19:56:57

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:06:21
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6) (b) (4)	12 Apr 2021 20:02:23 12 Apr 2021 20:01:15
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6) (b) (4)	12 Apr 2021 20:00:53 12 Apr 2021 20:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:59:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 19:59:15
Data point term sent to Coder User entered 'lisinopril'	System Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:58:15 03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'hypertension'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '10'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:39
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:57:33
User entered 'un UNK 1990'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 19:57:33

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:14:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 19:14:50

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE SODIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE SODIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:00:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:00:19
Data point term sent to Coder	System	03 Aug 2020 19:59:16
User entered 'nexium'	Traci Hull (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'gastroesophageal reflux disease'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '40'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:25
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:32
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 19:59:02
User entered 'un UNK 1995'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 19:59:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: PRAVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 20:02:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 20:02:10
Data point term sent to Coder	System	03 Aug 2020 20:01:16
User entered 'pravastatin'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'hyperlipidemia'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '40'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:29
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:00:37
User entered 'un UNK 1990'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 20:00:37

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:53
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: BECLOMETASONE DIPROPIONATE, PRODUCTSYNONYM: QVAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 11:49:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 11:49:23
Data point term sent to Coder	System	03 Aug 2020 20:03:19
User entered 'qvar'	Traci Hull (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'asthma'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '80'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (80 g) of this medication. Please review dose and dose unit and update as applicable (eg. 80 ug, etc.)' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 13:00:24
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (80 g) of this medication. Please review dose and dose unit and update as applicable (eg. 80 ug, etc.)' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 11:46:44
User entered 'ug (ug)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	26 Oct 2020 11:46:29
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose (80 g) of this medication. Please review dose and dose unit and update as applicable (eg. 80 ug, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:27:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:51:06
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:08:29
User entered 'g (g)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:07:55

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:29:30
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:35
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:18
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:02:26
User entered 'un UNK 2005'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '2'	System	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 20:02:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:05:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:05:02
Data point term sent to Coder	System	03 Aug 2020 20:04:22
User entered 'singulair'	Traci Hull (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'asthma'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '10'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 20:03:45
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:11
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:03:45
User entered 'un UNK 2005'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 20:03:45

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:54
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:00:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Sep 2020 07:06:49
Data point term sent to Coder	System	28 Sep 2020 13:10:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'SYMBICORT (BUDESONIDE AND FORMOTEROL)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	28 Sep 2020 13:10:51
Coding entries removed.	Tammy Kohn (b) (4)	28 Sep 2020 13:10:15
User entered 'SYMBICORT (budesonide (160 mcg) and formoterol (4.5 mcg)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	28 Sep 2020 13:10:15
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:06:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Aug 2020 20:06:03
Data point term sent to Coder	System	03 Aug 2020 20:05:23
User entered 'symbicort'	Traci Hull (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'CDM RQ: Per previous query, prophylaxis is still recorded as YES, however there is a corresponding condition for this medication. Please review and reconcile or explain.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 14:44:47
Query 'CDM RQ: Per previous query, prophylaxis is still recorded as YES, however there is a corresponding condition for this medication. Please review and reconcile or explain.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 20:58:54
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	08 Oct 2020 20:58:47
User opened query 'CDM RQ: Per previous query, prophylaxis is still recorded as YES, however there is a corresponding condition for this medication. Please review and reconcile or explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:09:19
User closed query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 15:09:19
Query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable.' answered with 'budesonide (160 mcg) and formoterol (4.5 mcg)' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:10:26

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Prophylaxis = Yes, however there is a corresponding entry on the Medical History CRF. It is unexpected for a medication to be given to prevent a condition the patient already has a diagnosis for. Please review and update the Con Med CRF if applicable. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:33:41
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'asthma'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '160/4.5'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 17:52:06
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:11:39
User entered 'ug (ug)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:11:34
User entered 'g (g)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:10:15
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 11:36:53
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:45
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:08:01
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:04:48
User entered 'un UNK 2005'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '2'	System	03 Aug 2020 20:04:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 20:04:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:00:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM, PRODUCTSYNONYM: XANAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:32:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:32:13
Data point term sent to Coder	System	03 Aug 2020 20:06:23
User entered 'xanx'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'anxiety'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0.5'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 20:05:25
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:05:25
User entered 'un UNK 2005'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	03 Aug 2020 20:05:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: MARIJUANA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:24
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: MARIJUANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:19:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Sep 2020 18:19:56
Data point term sent to Coder	System	30 Sep 2020 18:19:00
Coding entries removed.	Traci Hull (b) (4)	30 Sep 2020 18:18:43
User entered 'MEDICAL MARIJUANA' reason for change: New Information	(b) (4) Traci Hull (b) (4)	30 Sep 2020 18:18:43

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: CANNABIS SATIVA, PRODUCTSYNONYM: MARIJUANA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:15:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:15:08
Data point term sent to Coder	System	03 Aug 2020 20:08:24
User entered 'medical marijuanna'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'chronic back pain'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '3'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	04 Aug 2020 00:12:55
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	03 Aug 2020 20:07:29
User entered 'un UNK 2019'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	03 Aug 2020 20:07:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	03 Aug 2020 20:07:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
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)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
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)	28 Sep 2020 13:14:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	28 Sep 2020 13:14:46
Data point term sent to Coder	System	28 Sep 2020 13:14:01
User entered 'INFLUENZA VACCINE'	Tammy Kohn (b) (4)	28 Sep 2020 13:13:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'FLU PREVENTION'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0.5'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mL (mL)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once (ONCE)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Intramuscular (INTRAMUSCULAR)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '19 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '19 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:07:04
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	28 Sep 2020 13:13:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DEXAMETHAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DEXAMETHAZONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:35:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:35:05
Data point term sent to Coder	System	20 Jan 2021 16:33:14
User entered 'DEXAMETHAZONE'	Traci Hull (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SARS COVID19'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '6'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '16 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:17:12
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:13:51
User entered 'No (N)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:13:46
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:07:35
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '01 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	09 Apr 2021 18:13:46
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:49
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	20 Jan 2021 16:32:31

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Query 'Unable to verify - Not in source. ' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:04:33
User opened query 'Unable to verify - Not in source. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:03:57
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:56
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:35:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:35:06
Data point term sent to Coder	System	20 Jan 2021 16:34:15
User entered 'TYLENOL'	Traci Hull (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SARS COVID 19'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '500'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'as needed (PRN)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '06 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:17:22
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:14:43
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:14:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:07:43
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '30 Jan 2021' reason for change: Per Query Resolution	Traci Hull (b) (4)	09 Apr 2021 18:14:21
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:54
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:33:56

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: MONOCLONAL ANTIBODIES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:55
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ANTINEOPLASTIC AGENTS, ATC: OTHER ANTINEOPLASTIC AGENTS, ATC: MONOCLONAL ANTIBODIES, PRODUCT: MONOCLONAL ANTIBODIES - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:48:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 16:48:06
Data point term sent to Coder	System	20 Jan 2021 16:40:24
User entered 'MONOCLONAL ANTIBODIES'	Traci Hull (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SARS COVID 19'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 16:14:21
User entered '700' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:14:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:39:25
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Jan 2021 16:14:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Jan 2021 16:14:21
User entered 'mg (mg)' reason for change: New Information	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:14:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Jan 2021 16:39:25
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once (ONCE)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Intravenous (INTRAVENOUS)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '19 Jan 2021'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:08:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	20 Jan 2021 16:39:25

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:58
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: CLARITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 18:29:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Jan 2021 18:29:05
Data point term sent to Coder	System	21 Jan 2021 16:16:49
User entered 'CLARITHROMYCIN'	Traci Hull (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SARS COVID 19'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '500'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'twice daily (BID)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '11 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '16 Jan 2021'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '2'	System	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	21 Jan 2021 16:15:52

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Query 'Unable to verify - Unable to locate in source. ' canceled (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:03:21
Data point term sent to Coder	System	12 Apr 2021 20:02:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:00:57
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User opened query 'Unable to verify - Unable to locate in source. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 19:57:05
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Jan 2021 15:51:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Jan 2021 15:51:58
Data point term sent to Coder	System	23 Jan 2021 15:50:47
User entered 'ELIQUIS'	Tammy Kohn (b) (4) (b) (4)	23 Jan 2021 15:49:49

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'PREVENT PULMONARY EMBOLISM'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '5'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'twice daily (BID)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '21 Jan 2021'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	(b) (4) Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Tammy Kohn (b) (4)	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '2'	System	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	23 Jan 2021 15:49:49
DataPoint activated with code reason code Data required.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:23
DataPoint inactivated with code reason code Data not required.	Tammy Kohn (b) (4)	23 Jan 2021 15:47:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4) (b) (4)	12 Apr 2021 20:06:21
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6) (b) (4)	12 Apr 2021 20:02:26 12 Apr 2021 20:01:15
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6) (b) (4)	12 Apr 2021 20:00:58 12 Apr 2021 20:00:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:01:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:01:47
Data point term sent to Coder Coding entries removed.	System Tammy Kohn (b) (4) (b) (4)	17 Feb 2021 14:10:41 17 Feb 2021 14:10:35

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:45:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Feb 2021 20:45:31
Data point term sent to Coder	System	01 Feb 2021 20:45:07
User entered 'Colchicine'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'ACUTE INFECTIVE PERICARDITIS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Feb 2021 14:10:35
User entered 'Acute Pericarditis'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0.6'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4)	01 Feb 2021 20:44:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 11:26:16
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'UPDATED DATE TO MATCH THE AE' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	17 Feb 2021 14:10:56
User entered '30 Jan 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	17 Feb 2021 14:10:35
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:41:37
User entered '01 Feb 2021'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 18:08:16
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'NO STOP DATE AT THIS TIME AS PER DISCHARGE SUMMARY SUBJECT IS TO TAKE THE COLCHICINE FOR A PERIOD OF 90 DAY (3MONTHS)' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Mar 2021 14:14:38
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	28 Feb 2021 23:33:11
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	01 Feb 2021 20:44:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	12 Apr 2021 20:02:26 12 Apr 2021 20:01:15
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6)	12 Apr 2021 20:00:58 12 Apr 2021 20:00:35
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:21:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 14:21:28
Data point term sent to Coder User entered 'Naproxen'	System Jennifer Molstead (b) (4)	01 Feb 2021 20:46:07 01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Acute Pericarditis'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '500'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '30 Jan 2021' reason for change: Per Query Resolution	Traci Hull (b) (4)	09 Apr 2021 18:17:20
User entered '01 Feb 2021'	Jennifer Molstead (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:14:41
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CATARACT SURGERY' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	29 Mar 2021 12:55:31
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	29 Mar 2021 12:49:10
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:34:47
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:17:47
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:19:02
User entered '30 Jan 2021' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:17:20
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 11:26:41
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Mar 2021 12:49:10
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	29 Mar 2021 12:48:57
User entered '06 Feb 2021' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	29 Mar 2021 12:48:57
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Un-reviewed for Data Management.	(b) (4), (b) (6)	07 Apr 2021 11:26:37
Reviewed for Data Management.	(b) (4), (b) (6)	07 Apr 2021 11:26:33
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '2'	System	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:11
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	01 Feb 2021 20:46:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder DataPoint activated with code reason code Data required.	System (b) (4), (b) (6)	12 Apr 2021 20:02:26 12 Apr 2021 20:01:15
Data point term sent to Coder DataPoint inactivated with code reason code Data not required.	System (b) (4), (b) (6)	12 Apr 2021 20:00:58 12 Apr 2021 20:00:35
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 00:11:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Feb 2021 00:11:33
Data point term sent to Coder User entered 'nitro glycerin'	System Jennifer Molstead (b) (4)	01 Feb 2021 20:49:09 01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'acute pericarditis'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0.4'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '30 Jan 2021'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:49:08
User entered '30 Jan 2021' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	01 Feb 2021 20:49:08
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Feb 2021 20:49:02
User entered '30 Jan 21' (non-conformant).	Jennifer Molstead (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:17
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	System	01 Feb 2021 20:49:02

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:25
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User closed query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #16/ (Start date 21JAN2021 - Stop date ONGOING). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 11:27:18
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #16/ (Start date 21JAN2021 - Stop date ONGOING). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4)	17 Feb 2021 14:16:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with CM #16/ (Start date 21JAN2021 - Stop date ONGOING). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 08:43:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	05 Feb 2021 00:26:33
Data point term sent to Coder	System	04 Feb 2021 14:59:26
User entered 'PREDNISONE'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	(b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '40'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '21 Jan 2021'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '25 Jan 2021'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4)	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:23
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 14:58:45
DataPoint activated with code reason code Data required.	Traci Hull (b) (4)	04 Feb 2021 14:57:50
DataPoint inactivated with code reason code Data not required.	Jennifer Molstead (b) (4)	01 Feb 2021 20:54:29

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:00
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:33
Data point term sent to Coder	System	04 Feb 2021 15:00:28
User entered 'PREDNISONONE'	Traci Hull (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '35'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '26 Jan 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '28 Jan 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:32
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 14:59:40

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:34
Data point term sent to Coder	System	04 Feb 2021 15:01:28
User entered 'PREDNISONONE'	Traci Hull (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '30'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '29 Jan 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '31 Jan 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:36
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 15:01:00

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:26
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:34
Data point term sent to Coder	System	04 Feb 2021 15:02:30
User entered 'PREDNISONONE'	Traci Hull (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '25'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1 Feb 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '3 Feb 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 15:01:48

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:27
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:02
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 00:26:35
Data point term sent to Coder	System	04 Feb 2021 15:03:31
User entered 'PREDNISONE'	Traci Hull (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '20'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '4 Feb 2021'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:18:15
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'UPDATED' (Site from DM).	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:20:14
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	09 Apr 2021 18:20:08
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:07:53
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '06 Feb 2021' reason for change: Per Query Resolution	Traci Hull (b) (4)	09 Apr 2021 18:20:08
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:45
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 15:03:10

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN EC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 00:55:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	09 Feb 2021 00:55:39
Data point term sent to Coder	System	08 Feb 2021 16:27:52
Coding entries removed.	Traci Hull (b) (4)	08 Feb 2021 16:27:32
User entered 'COATED ASPIRIN' reason for change: New Information	Traci Hull (b) (4)	08 Feb 2021 16:27:32

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 15:08:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Feb 2021 15:08:51
Data point term sent to Coder	System	04 Feb 2021 15:08:34
User entered 'ASPIRIN'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'COVID'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '325'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '3 Feb 2021' reason for change: New Information	Traci Hull (b) (4)	09 Apr 2021 18:21:44
User entered '4 Feb 2021'	Traci Hull (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User closed query 'PER DM CLR: RE-QUERY: Response noted. However, since corresponding AE has resolved, kindly consider updating Ongoing and stop date as applicable or clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Apr 2021 07:28:22
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:32:43
Query 'PER DM CLR: RE-QUERY: Response noted. However, since corresponding AE has resolved, kindly consider updating Ongoing and stop date as applicable or clarify. Thank you.' answered with 'UPDATED DATE AND STOPPED THE MEDICATION' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:32:54
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:32:32
Signature has been broken.	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:32:32
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:32:32
User opened query 'PER DM CLR: RE-QUERY: Response noted. However, since corresponding AE has resolved, kindly consider updating Ongoing and stop date as applicable or clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:00:53
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:00:53
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4)	09 Apr 2021 18:21:35
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 11:08:01
User entered 'Yes (Y)'	Traci Hull (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:32:45
DataPoint Un-verified.	Tammy Kohn (b) (4)	16 Apr 2021 11:32:32
Signature has been broken.	(b) (4) Tammy Kohn (b) (4)	16 Apr 2021 11:32:32
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4) Tammy Kohn (b) (4)	16 Apr 2021 11:32:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	04 Feb 2021 15:08:06

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:09:52
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	04 Feb 2021 15:08:06

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:30
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 13:38:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	09 Feb 2021 13:38:46
Data point term sent to Coder	System	09 Feb 2021 13:37:26
User entered 'PREDNISONONE'	Traci Hull (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User closed query 'Per source this is 15mg. Please verify and update. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:44:19
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:44:08
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
Query 'Per source this is 15mg. Please verify and update. Thank you. ' answered with 'updated' (Site from CRA).	Tammy Kohn (b) (4)	14 Apr 2021 18:16:03
DataPoint Un-verified.	Tammy Kohn (b) (4)	14 Apr 2021 18:15:51
User entered '15' reason for change: Data Entry Error	Tammy Kohn (b) (4)	14 Apr 2021 18:15:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
User opened query 'Per source this is 15mg. Please verify and update. Thank you. ' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:02:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '10'	Traci Hull (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '07 Feb 2021'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '09 Feb 2021'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:03
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	09 Feb 2021 13:36:36

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:56
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Feb 2021 13:33:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Feb 2021 13:33:52
Data point term sent to Coder	System	12 Feb 2021 13:33:10
User entered 'PREDNISONONE'	Traci Hull (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '10'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '10 Feb 2021'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '12 Feb 2021'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:14
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	12 Feb 2021 13:32:20

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 21:20:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Apr 2021 21:20:57
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:06:21
Data point term sent to Coder	System	12 Apr 2021 20:02:29
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
Data point term sent to Coder	System	12 Apr 2021 20:01:07
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Feb 2021 12:53:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Feb 2021 12:53:03
Data point term sent to Coder	System	15 Feb 2021 12:51:58
User entered 'PREDNISONE'	Traci Hull (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'SYMPTOMATIC COVID'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '5'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'mg (mg)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'once daily (QD)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'Oral (ORAL)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered empty.	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '13 Feb 2021'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '0'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '15 Feb 2021'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 20:06:21
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '1'	System	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered 'I'	System	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:10:19
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Apr 2021 20:01:15
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Apr 2021 20:00:35
User entered '804 (804)'	System	15 Feb 2021 12:51:16

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:12
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS WITH NO EFFECT ON URIC ACID METABOLISM, PRODUCT: COLCHICINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:32:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 11:32:52
Data point term sent to Coder	System	16 Apr 2021 11:32:15
User entered 'COLCHICINE' reason for change:	Tammy Kohn (b) (4)	16 Apr 2021 11:31:25
Data Entry Error	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 11:31:14
User entered 'Colchicine - 0.12mg, PO, Bid; Acute Pericarditis, 01Feb2021'	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:33:14
User entered 'No (N)'	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:33:20
User entered 'Acute Pericarditis'	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:22
User entered '0.12'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:24
User entered 'mg (mg)'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:33:25
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:27
User entered 'twice daily (BID)'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:28
User entered empty.	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:30
User entered 'Oral (ORAL)'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:32
User entered empty.	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

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

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:34
User entered '01 Feb 2021'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:35
User entered '0'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:37
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 19:33:39
User entered empty.	Tammy Kohn (b) (4) (b) (4)	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 19:33:41
User entered 'No (N)'	Tammy Kohn (b) (4)	16 Apr 2021 11:31:12
	(b) (4)	

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:28:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 11:31:12

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:28:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:40
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:07:02
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	23 Jan 2021 15:47:22
User entered 'No (N)'	Traci Hull (b) (4)	03 Aug 2020 20:09:07

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:11:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered '21 Jan 2021'	Tammy Kohn (b) (4)	23 Jan 2021 15:48:10
	(b) (4)	

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:11:57
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'CHEST XRAY'	Tammy Kohn (b) (4)	23 Jan 2021 15:48:10
	(b) (4)	

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:11:59
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Tammy Kohn (b) (4)	23 Jan 2021 15:48:10
	(b) (4)	

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:28:54

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 20:12:01
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	23 Jan 2021 15:48:10
	(b) (4)	

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:28:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered '30 Jan 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Feb 2021 20:46:32

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:28:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'ECG'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:46:32

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	01 Feb 2021 20:46:32

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:28:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	01 Feb 2021 20:46:32
	(b) (4)	

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:28:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered '30 Jan 2021'	(b) (4) Jennifer Molstead (b) (4)	01 Feb 2021 20:47:02

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:28:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'Cardiac Catherization'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:47:02

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:28:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	01 Feb 2021 20:47:02

US3402204

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:28:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:26:56
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:29:52
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:30:57
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	01 Feb 2021 20:47:02
	(b) (4)	

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'USA-US059-2021-MRNA-1273-P301000004'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Frank'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Eder'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '1290 Upper Front Street'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Binghamton'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'NY'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '13901'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'US'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 19:44:51
User entered '3'	System	09 Mar 2021 13:44:21
User entered '2'	System	08 Feb 2021 22:07:05
User entered '1'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'USA-US059-2021-MRNA-1273-P301000004'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Frank'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Eder'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '1290 Upper Front Street'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Binghamton'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'NY'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '13901'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'US'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 19:44:51
User entered '3'	System	09 Mar 2021 13:44:21
User entered '2'	System	08 Feb 2021 22:07:05
User entered '1'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered '19/Jan/2021 20:44'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'I'	(b) (4), (b) (6)	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'USA-US059-2021-MRNA-1273-P301000004'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Frank'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Eder'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '1290 Upper Front Street'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Binghamton'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'NY'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '13901'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'US'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 19:44:51
User entered '3'	System	09 Mar 2021 13:44:21
User entered '2'	System	08 Feb 2021 22:07:05
User entered '1'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered '08/Feb/2021 17:07'	System	08 Feb 2021 22:07:05

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered 'I'	(b) (4), (b) (6)	08 Feb 2021 22:07:05

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'USA-US059-2021-MRNA-1273-P301000004'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Frank'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Eder'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '1290 Upper Front Street'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Binghamton'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'NY'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '13901'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'US'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 19:44:51
User entered '3'	System	09 Mar 2021 13:44:21
User entered '2'	System	08 Feb 2021 22:07:05
User entered '1'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered '09/Mar/2021 08:44'	System	09 Mar 2021 13:44:21

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 13:44:21

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'USA-US059-2021-MRNA-1273-P301000004'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'No (N)'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Frank'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Eder'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '1290 Upper Front Street'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'Binghamton'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered 'NY'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 20:44:30
User entered '13901'	System	19 Jan 2021 20:43:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 22:06:50
User entered 'US'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	23 Mar 2021 19:44:51
User entered '3'	System	09 Mar 2021 13:44:21
User entered '2'	System	08 Feb 2021 22:07:05
User entered '1'	System	19 Jan 2021 20:44:38

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered '23/Mar/2021 12:44'	System	23 Mar 2021 19:44:51

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:19
User entered 'I'	(b) (4), (b) (6)	23 Mar 2021 19:44:51

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'USA-US059-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User entered 'Yes (Y)'	System	15 Apr 2021 16:17:29
Un-reviewed for Safety.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Frank'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Eder'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '1290 Upper Front Street'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Binghamton'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'NY'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '13901'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'US'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 18:17:41
User entered '3'	System	09 Mar 2021 16:39:17
User entered '2'	System	09 Feb 2021 16:29:06
User entered '1'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'USA-US059-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User entered 'Yes (Y)'	System	15 Apr 2021 16:17:29
Un-reviewed for Safety.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Frank'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Eder'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '1290 Upper Front Street'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Binghamton'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'NY'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '13901'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'US'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 18:17:41
User entered '3'	System	09 Mar 2021 16:39:17
User entered '2'	System	09 Feb 2021 16:29:06
User entered '1'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
User entered '02/Feb/2021 13:46'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'I'	(b) (4), (b) (6)	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'USA-US059-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User entered 'Yes (Y)'	System	15 Apr 2021 16:17:29
Un-reviewed for Safety.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Frank'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Eder'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '1290 Upper Front Street'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Binghamton'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'NY'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '13901'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'US'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 18:17:41
User entered '3'	System	09 Mar 2021 16:39:17
User entered '2'	System	09 Feb 2021 16:29:06
User entered '1'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
User entered '09/Feb/2021 11:29'	System	09 Feb 2021 16:29:06

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'I'	(b) (4), (b) (6)	09 Feb 2021 16:29:06

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'USA-US059-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User entered 'Yes (Y)'	System	15 Apr 2021 16:17:29
Un-reviewed for Safety.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Frank'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Eder'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '1290 Upper Front Street'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Binghamton'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'NY'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '13901'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'US'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 18:17:41
User entered '3'	System	09 Mar 2021 16:39:17
User entered '2'	System	09 Feb 2021 16:29:06
User entered '1'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
User entered '09/Mar/2021 08:39'	System	09 Mar 2021 16:39:17

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:28:54

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.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 16:39:17

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'USA-US059-2021-MRNA-1273-P301000007'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:17:45
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:36:00
User entered 'Yes (Y)'	System	15 Apr 2021 16:17:29
Un-reviewed for Safety.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Un-verified.	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	15 Apr 2021 16:17:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Yes (Y)'	System	02 Feb 2021 13:45:39

US3402204

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

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Form: Safety Report Form

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'No (N)'	System	02 Feb 2021 13:45:39

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Frank'	System	02 Feb 2021 13:45:39

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Eder'	System	02 Feb 2021 13:45:39

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[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '1290 Upper Front Street'	System	02 Feb 2021 13:45:39

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[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'Binghamton'	System	02 Feb 2021 13:45:39

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[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered 'NY'	System	02 Feb 2021 13:45:39

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[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	02 Feb 2021 13:46:22
User entered '13901'	System	02 Feb 2021 13:45:39

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 19:52:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 16:29:10
User entered 'US'	System	02 Feb 2021 13:46:28

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Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:28:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	19 Apr 2021 18:17:41
User entered '3'	System	09 Mar 2021 16:39:17
User entered '2'	System	09 Feb 2021 16:29:06
User entered '1'	System	02 Feb 2021 13:46:28

US3402204

Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:28:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 03:43:06
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
User entered '19/Apr/2021 14:17'	(b) (4) System	19 Apr 2021 18:17:41

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Folder: SAE USA-US059-2021-MRNA-1273-P301000007

Form: Safety Report Form (4)

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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)	27 Apr 2021 03:43:08
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:47:55
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:17:45
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 18:17:41